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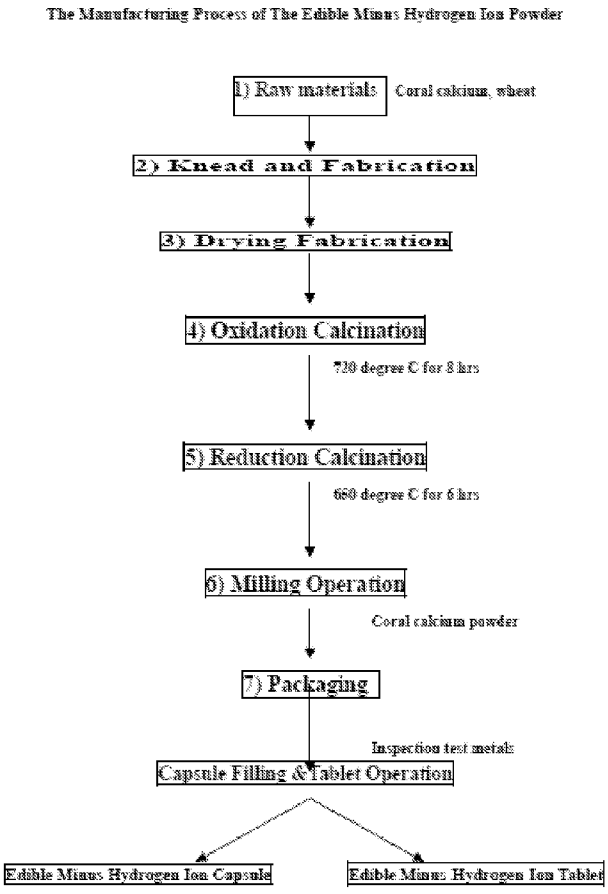
(54) Title: COMPOSITION, METHOD FOR ITS MANUFACTURE AND USE THEREOF

(57) Abstract: A composition, a method for its manufacture and uses thereof is disclosed.

Figure 1



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COMPOSITION, METHOD FOR ITS MANUFACTURE AND USE THEREOF

Field of the Invention

This invention pertains in general to the field of pharmaceutical compositions, methods for their manufacture and use thereof. The compositions may be used to treat e.g. cancer, pain, diabetes, osteoporosis and skin diseases such as dermatitis. In particular said compositions emit hydrogen.

Background of the Invention

Inhibitory effects of SSRIs on IFN-γ induced microglial activation through the regulation of intracellular calcium has been disclosed see e.g. Hideki Horikawa et al, Progress in Neuro-Psychopharmacology & Biological Psychiatry 34, (2010) page 1306-1316.

Further it has been disclosed that glia are nervous caretakers whose nurturing can go to far, see "New culprits in chronic pain", R. Douglas Fields, Neuroscience, Scientific American, Nov. 2009 page 30-37.

Manufacture of a magnetic ceramic ball for water purifier is further disclosed in JP2002382862A. Said ball generates active hydrogen. The process comprises mainly the following steps:

1) Water is added and mulled to a composition comprising 48 % zeolite, 33% of pottery clay, 3% of coral calcium and 48 % of Fe_2O_3
2) The mixture is fabricated and the result is that the composition is provided in spheres with a particle size of 10 – 15 mm. These spheres further are dried during 2 to 3 days
3) The spheres are then oxidation calcinated at 950° in the atmosphere for 8 hours.
4) Then the spheres are reduction calcinated at 950° in a gas consisting of a mixture of N_2 (nitrogen gas) and H_2 (hydrogen gas) at a ratio of 90%: 10 % during 12 hours.
5) Finally the spheres are irradiated during 5 seconds intervals at 2T Gausses (20,000 gausses) magnetism.

Manufacturing of a hydrogen ion for gelatin capsule or sugar coating, which comprises adding water to coral calcium powder, kneading with wheat flour, molding, oxidation-baking, dry-casting and powdering is disclosed in JP200458446A.

The drinking and eating of the minus hydrogen ions are said to be having an effect on overweight, prevention of cancer, in addition to an improvement of geriatric disorders, such as hypertension, high cholesterol, hyperlipemia and diabetes.

There are 4 stages in the manufacturing process with a 3rd stage wherein the prepared material is placed in a high heat, oxygen-free reduction environment with a mixture of nitrogen gas and hydrogen at a ratio of 90 % (N_2) : 10 (H_2). The hydrogen gas ($H_2\uparrow$) enters a plasma state becoming polarized and ionized

to generate ($H_2\uparrow$) $\leftrightarrow$ H^+ +: H^-. CaH_2 is produced as the temperature inside the kiln returns to normal, thereby finishing the process of calcination and reduction.

CaH_2 is a metal hydride. It appears that the manufacturing process synthesizes the metal hydride by a direct reaction between the solid material and hydrogen gas. The reaction between the solid and gas can be written as follows:

M (solid) + H_2 (gas)$\rightarrow$ MH or MH_2

When CaO is formed in the second stage of the manufacturing process, it is reduced by H_2 and becomes CaH_2. The H_2O evaporates. As a result CaH_2 as an ionic bonding hydride (saline hydride) is formed. The monovalent M becomes MH and the bivalent becomes MH_2.

When the CaH_2 is exposed to water it appears there is a reaction between Ca^{2+} + $2H^-$ and $2H^-$ + $2H^+$ $\leftrightarrow$ 2 $H_2\uparrow$. When a metal hydride is exposed to water, a protium reaction occurs on the surface of the stereo structure and the electron charge exchange between hydrogen atoms and the water around it creates an alkaline environment:

($H^+ \leftrightarrow H^0$, $H^0 \leftrightarrow H^-$, $H_2 \leftrightarrow 2H^0$, $H_2 \leftrightarrow 2H^-$).

Also an eau de toilette is disclosed in WO2010/095279 which includes alkali reducing mineral ion water and process for its production.

However coral is a limited material on earth.

Hence, there is a need for a new composition emitting hydrogen, and method for its manufacture, which is not limited to the amount of coral present.

Summary of the Invention

Accordingly, embodiments of the present invention preferably seeks to mitigate, alleviate or eliminate one or more deficiencies, disadvantages or issues in the art, such as the above-identified, singly or in any combination by providing a pharmaceutical composition, method for its manufacture and use thereof according to the appended patent claims.

According to a first aspect of the invention, a hydrogen emitting composition for pharmaceutical use comprising a magnesium compound is provided.

According to a second aspect of the invention, a method for manufacturing a magnesium hydride set out in a preferred embodiment of the first aspect for use in a composition according to the first aspect comprising the following steps:

a) providing magnesium oxide,

b) performing a reduction calcination of said magnesium oxide at about 650 °C and during about 6 hours under a gas atmosphere being a mix of N_2 and H_2, with a ratio of 90%:10%, and

c) milling of the reduction calcination end product and

d) optionally storing said milled reduction calcination end product and also optionally, filling the product obtained in step c) in containers, is provided.

According to a third aspect of the invention, a magnesium hydride obtainable by the method according to the second aspect is provided.

According to a fourth aspect of the invention, a method for manufacturing a composition set out as a preferred embodiment of the first aspect comprising the following steps:

e) mixing magnesium hydride or magnesium metal with a minus hydrogen ion material, all in powder form, and

f) filling the mix obtained in step e) into containers or into capsules, or tableting said mix into tablets, and optionally

g) if mix filled into capsules or tableted into tablets, packing said capsules or tablets in a container,

wherein preferably the magnesium hydride in powder form is a magnesium hydride according to the third aspect, is provided.

According to a fifth aspect of the invention, a method for manufacturing a composition set out as a preferred embodiment of the first aspect comprising the following steps:

h) mixing a magnesium hydride, a calcium hydride and a halogen chloride, preferably NaCl, all in powder form,

i) distributing the mix of step h) into a liquid, preferably water, whereby letting the suspension to rest, and optionally

j) filtering the suspension and

k) filling the filtered liquid into a container or into bottles,

wherein preferably the magnesium hydride in powder form is a magnesium hydride according to the third aspect, is provided.

According to a sixth aspect of the invention, a liquid obtainable by the method according the fifth aspect
is provided.

According to a seventh aspect of the invention, a

method for manufacturing a composition set out as a preferred embodiment of the first aspect comprising the following steps:

l) mixing, a magnesium metal, preferably in powder form, magnetic ceramic balls and activated carbon, preferably in powder form,

m) filling said mix of step l) into a perforated container, preferably in the form of a stick, allowing a liquid when said container, preferably a stick, is submerged into a liquid to penetrate into said perforated container and

closing the entrance for filling of said container, is provided.

According to an eighth aspect of the invention, a container obtainable by the method according the seventh aspect is provided.

According to a ninth aspect of the invention, a method for producing a hydrogen plasma water involving the following steps:

o) washing one or more compositions according to the a preferred embodiment of the first aspect, preferably in the form of sticks, in a weak acidic liquid, preferably vinegar, and

p) inserting one of more of said washed compositions above in water and letting the water rest,

q) withdrawing said washed compositions from the water, and optionally

r) filling the water into a container or into bottles, is provided.

According to a tenth aspect of the invention, water obtainable by the method according the ninth aspect is provided.

According to an eleventh aspect of the invention, use of a composition according to a preferred embodiment of the first aspect for producing a hydrogen plasma water is provided.

According to a twelfth aspect of the invention, a method for producing a minus hydrogen ion material as set out in a preferred embodiment of the first aspect involving the following steps:

s) mixing a liquid, coral calcium powder and wheat, and preferably also silica, and forming into a dumpling like shape,

t) drying,

u) performing an oxidation calcination on the product of step t) at 720 °C and during about 8 hours,

v) performing a reduction calcination on the product of step u) at 650 °C and during about 6 hours under a gas atmosphere being a mix of N_2 and H_2, with ratio 90%:10%, and

w) milling the product of step v) and optionally,

x) filling the milled product obtained in step w) into containers or into capsules, or tableting said milled product into tablets, and also optionally if the milled product obtained in step w) filled into capsules or tableted into tablets, packing said capsules or tablets in a container, is provided.

According to a thirteenth aspect of the invention, a minus hydrogen ion material obtainable by the method according the twelfth aspect is provided.

According to a fourteenth aspect of the invention,

a method for producing (a) magnetic ceramic ball(s) as set out in a preferred embodiment of the first aspect involving the following steps:

y) mixing a clay, an iron oxide, coral calcium powder and a zeolite, and preferably also a liquid,

z) drying and forming the mix of step y) into (an) essentially spherical portion(s),

aa) performing an oxidation calcination on the product of step z) at 720 °C and during about 8 hours,

bb) performing a reduction calcination on the product of step aa) at 650 °C and during about 6 hours under a gas atmosphere being a mix of N_2 and H_2, with ratio 90%:10%, and

cc) performing a magnetizing process on the product of step bb) and optionally,

dd) filling the product obtained in step cc) into a container, is provided.

According to a fifteenth aspect of the invention, a magnetic ceramic ball obtainable by the method according the fourteenth aspect is provided.

According to a sixteenth aspect of the invention,

a method for treatment of an animal or human body is provided whereby the composition according to the first aspect is used.

According to a seventeenth aspect of the

invention, composition comprising magnesium for use in treating an indication or in a therapy as set out in the sixteenth aspect of the invention is provided.

According to a eighteenth aspect of the

invention, composition comprising a magnesium hydride according to the third aspect of the invention for use in treating an indication or in a therapy as set out in the sixteenth aspect of the invention is provided.

According to a nineteenth aspect of the

invention, liquid according to the sixth aspect of the invention for use in treating an indication or in a therapy as set out in the sixteenth aspect of the invention is provided.

According to a twentieth aspect of the

invention, container according to the seventh aspect of the invention for use in treating an indication or in a therapy as set out in the sixteenth aspect of the invention is provided.

According to a twenty-first aspect of the invention, water according to the tenth aspect of the invention for use in treating an indication or in a therapy as set out in the sixteenth aspect of the invention is provided.

According to a twenty-second aspect of the invention, a magnetic ceramic ball according to the fifteenth aspect of the invention for use in treating an indication or in a therapy as set out in the sixteenth aspect of the invention is provided.

According to a twenty-third aspect of the invention, a kit comprising a weak acidic liquid and a container according to the eighth aspect, preferably in the form of a stick, is provided.

According to a twenty-fourth aspect of the invention, a method in accordance with the description and the drawings is provided.

It should be emphasized that the term “comprises/comprising” when used in this specification is taken to specify the presence of stated features, steps or components but does not preclude the presence or addition of one or more other features, steps, components or groups thereof.

These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference also being made to the accompanying drawings.

Description of embodiments

Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention.

It is intended throughout the present description that the expression "mitochondrial disease” embraces any disease that impact the coordinated synthesis and regulation of energy metabolism. These diseases go by a variety of names. They may also be referred to as inherited respiratory chain diseases of the mitochondria as a way of underscoring the role of the mitochondria in oxygen consumption or respiration. Said disease may further be an orphan mitochondrial disease. A further example of such an orphan disease is Duchenne muscular dystrophy.

Mitochondria may malfunction in a number of ways, but one reason may be a genetic error. Inherited mitochondrial disease can arise from defects in genes located in either the nuclear or the mitochondrial genome.

Mitochondrial diseases may cause severe, often life-threatening disabilities. As the brain and the muscles consume disproportionate amount of energy and are afflicted early in the course of these diseases, said diseases are often referred to neuromuscular diseases. Mitochondrial diseases may also impair normal function of the heart, kidneys, liver, intestine and pancreas. Children and young adults with said diseases may be very sick, and succumb to progressive aging syndrome- in effect, accelerated aging.

It is intended throughout the present description that the expression “a weak acidic liquid” any acidic liquid which is edible. One non-limiting example is acetic acid. A preferred weak acidic liquid is vinegar.

According to a preferred embodiment of the first aspect of the invention the composition for pharmaceutical use according to the first aspect the magnesium compound is a magnesium hydride or a magnesium metal.

According to a preferred embodiment of the first aspect of the invention the composition comprises a magnesium hydride and a minus hydrogen ion material, both preferably in powder form.

According to a preferred embodiment of the first aspect of the invention the composition comprises a magnesium metal and a minus hydrogen ion material, both preferably in powder form.

According to a preferred embodiment of the first aspect of the invention the composition comprises a magnesium hydride, a calcium hydride and a halogen chloride, preferably NaCl, all preferably in powder form.

According to a preferred embodiment of the first aspect of the invention the composition comprises a magnesium metal, preferably in powder form, magnetic ceramic balls and activated carbon, preferably in powder form.

According to a preferred embodiment of the first aspect of the invention the composition is in liquid form or in solid form.

According to a preferred embodiment of the first aspect of the invention the solid form is a capsule, tablet or a powder for suspending or immersing.

According to a preferred embodiment of the first aspect of the invention the tablet also comprises crystalline cellulose and sucrose fatty acid.

According to a preferred embodiment of the first aspect of the invention the powder for immersing is contained in a stick.

According to a preferred embodiment of the first aspect of the invention the liquid form is a filtered liquid or a suspension.

According to a preferred embodiment of the first aspect of the invention the composition also comprises CoQ10 or an analogue thereof. CoQ10 is also known as Coenzyme Q_{10}, ubiquinone, ubidecarenone or coenzyme Q, i.e. (2-[(2*E*,6*E*,10*E*,14*E*,18*E*,22*E*,26*E*,30*E*,34*E*)-3,7,11,15,19,23,27,31,35,39-decamethyltetraconta - 2,6,10,14,18,22,26,30,34,38-decaenyl]-5, 6-dimethoxy-3-methylcyclohexa-2,5-diene -1,4- dione).

According to a preferred embodiment of the first aspect of the invention wherein said analogue (i.e. CoQ10 analogue) is alpha-tocopherol quinone, tocotrienol quinone, tocotrienol hydroquinone or Idebenone. Idebenone is also known as 2-(10-hydroxydecyl)-5,6-dimethoxy-3-methyl-cyclohexa-2,5-diene-1,4-dione; sold under trade names Catena and Sovrima). The composition may also comprise CoQ10, alpha-tocopherol quinone and Idebenone together or two of these at a time.

According to a preferred embodiment to the first aspect of the invention the composition also comprises a vitamin and/or an antioxidant besides CoQ10 or an analogue set out above.

According to a preferred embodiment of the first aspect of the invention the composition also comprises 4-(p-quinolyl)-2-hydroxybutanamide, 2-(3-hydroxy-3-methylbutyl)-6-(het)aryl-p-quinone or 2-(3-hydroxy-3-methylbutyl)-3-(het)aryl-p-quinone or a derivative thereof of said compounds.

According to a preferred embodiment of the sixteenth aspect of the invention the therapy is against cancer, wherein said cancer preferably is terminal cancer.

According to a preferred embodiment of the sixteenth aspect of the invention the therapy is against one or more tumors appearing on the surface of an animal or human body and/or inside of an animal or human body.

According to a preferred embodiment of the sixteenth aspect of the invention the tumor(s) appearing on the surface of an animal or human body is a melanoma or non-melanoma cancer.

According to a preferred embodiment of the sixteenth aspect of the invention the tumor(s) inside of an animal or human body, is one or more of a retina blastoma cancer, pancreatic cancer, liver cancer, prostate cancer, ovarian cancer, gastric cancer, bile duct cancer, bladder cancer, colon cancer, epithelial cancer, breast cancer, oral cancer, nasal cancer, osteosarcomas, head cancer, neck cancer, brain cancer, peritoneal cancer, esophageal cancer, kidney cancer, lung cancer, cancer in the nerves, barretts esophagus, basal cell carcinoma, cervical cancer, esophagus cancer, gastrointestinal cancer, gynecology diseases, testicular cancer, rectal cancer and hpv warts.

According to a preferred embodiment of the sixteenth aspect of the invention the therapy is against pain.

According to a preferred embodiment of the

sixteenth aspect of the invention the therapy is against a geriatric disorder. The geriatric disorder is preferably one or more of hypertension, cholesterol, hyperlipemia and diabetes, most preferred hyperlipemia.

According to a preferred embodiment of the sixteenth aspect of the invention the therapy is against hyperlipemia.

According to a preferred embodiment of the sixteenth aspect of the invention the therapy is promoting hormonal secretion.

According to a preferred embodiment of the sixteenth aspect of the invention the dosage regime is 1 capsule or tablet a day. Preferably said capsule or tablet is obtained from a method according to the fourth aspect or the twelfth aspect of the invention.

According to a preferred embodiment of the sixteenth aspect of the invention the dosage regime is two capsules before exercise. Preferably said capsule or tablet is obtained from a method according to the fourth aspect or the twelfth aspect of the invention.

According to a preferred embodiment of the sixteenth aspect of the invention the indication is hair loss.

According to a preferred embodiment of the sixteenth aspect of the invention the indication is stress symptoms.

According to a preferred embodiment of the sixteenth aspect of the invention the indication is loss of sexual capacity.

According to a preferred embodiment of the sixteenth aspect of the invention the indication is an inflammation.

According to a preferred embodiment of the sixteenth aspect of the invention the indication is a mitochondrial disease.

According to a preferred embodiment of the sixteenth aspect of the invention the mitochondrial disease is an orphan mitochondrial disease, preferably Duchenne muscular dystrophy or progressive aging syndrome.

According to a preferred embodiment of the sixteenth aspect of the invention the mitochondrial disease is associated with a point mutation of the DNA, preferably mitochondrial myopathy, encephalopathy, lactic acidosis and stroke-like episodes (MELAS syndrome), Kearns-Sayre Syndrome (KSS), primary progressive multiple sclerosis , Leber's hereditary optic neuropathy, dominant optic atrophy or Friedrich´s ataxia.

According to a preferred embodiment of the

sixteenth aspect of the invention the mitochondrial disease is Huntington´s disease, adult neurodegenerative disease, amyotrophic lateral sclerosis (ALS), Parkinson's disease or pervasive developmental disorder such as autism.

According to a preferred embodiment of the sixteenth aspect of the invention the mitochondrial disease is blindness.

According to a preferred embodiment of the sixteenth aspect of the invention the therapy is against osteoporosis, arthritis or chronic anti-inflammatory diseases.

According to a preferred embodiment of the sixteenth aspect of the invention the therapy is against a skin disease selected from the group comprising serious atopic dermatitis, Congenital Epidermolysis Bullosa, psoriasis, eczema or inflammatory bowel disease, as like ulcerative colitis and haemorrhoids etc. and combinations thereof.

According to a preferred embodiment of the sixteenth aspect of the invention the the dosage regime is four to six capsules a day in case of a skin disease as set out above. Preferably said capsule is obtained from a method according to the fourth aspect or the twelfth aspect of the invention.

According to a preferred embodiment of the sixteenth aspect of the invention the therapy is against obesity.

According to a preferred embodiment of the seventeenth aspect of the invention the composition comprises a magnesium hydride or a magnesium metal, for use in treating an indication or in therapy as set out in the sixteenth aspect of the invention.

For the sixteenth aspect also the magnesium hydride according to the third aspect may be used, the liquid according to the sixth aspect may be used, the container according to the eighth aspect may be used, the water according to the tenth aspect may be used, the minus hydrogen material according to the thirteenth aspect may be used or the magnetic ceramic ball according to the fifteenth aspect may be used.

The compositions of the invention can also include conventional auxiliaries such as surface anaesthetics, sunscreens, flavours, scents, emollients or skin tone colourants and masks.

Although the key ingredients present in the compositions of the present invention are as set out in the first aspect of the invention, the inclusion of other excipients in the composition may be useful. These excipients may be utilized with the composition in order to formulate the composition into tablets, capsules, suspensions, powders for suspension and the like.

One useful class of excipients is surfactants. Suitable surfactants include fatty acid and alkyl sulfonates; commercial surfactants such as benzethanium chloride (HYAMINE(R) 1622, available from

Lonza, Inc., Fairlawn, N.J.); DOCUSATE SODIUM (available from Mallinckrodt Spec. Chem., St. Louis, MO); polyoxyethylene sorbitan fatty acid esters (TWEEN(R), available from ICI Americas Inc., Wilmington, DE); LIPOSORB(R) P-20 (available from Lipochem Inc., Patterson NJ); CAPMUL(R) POE-0 (available from Abitec Corp., Janesville, WI), and natural surfactants such as sodium taurocholic acid, 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphocholine, lecithin, and other phospholipids and mono- and diglycerides. Such materials can advantageously be employed to increase the rate of dissolution by facilitating wetting, thereby increasing the maximum dissolved concentration, and also to inhibit crystallization or precipitation of drug by interacting with the dissolved drug by mechanisms such as complexation, formation of inclusion complexes, formation of micelles or adsorbing to the surface of solid drug. These surfactants may comprise up to 5 wt% of the composition.

The addition of pH modifiers such as acids, bases, or buffers may also be beneficial, retarding or enhancing the rate of dissolution of the composition, or, alternatively, helping to improve the chemical stability of the composition.

Other conventional formulation excipients may be employed in the compositions of this invention, including those excipients well-known in the art (e.g., as described in Remington's Pharmaceutical Sciences (16th ed. 1980). Generally, excipients such as fillers, disintegrating agents, pigments, binders, lubricants, glidants, flavorants, and so forth may be used for customary purposes and in typical amounts without adversely affecting the properties of the compositions. These excipients may be utilized after the drug composition has been formed, in order to formulate the composition into tablets, capsules, suspensions, powders for suspension, and the like.

Examples of matrix materials, fillers, or diluents include lactose, mannitol, xylitol, dextrose, sucrose, sorbitol, compressible sugar, microcrystalline cellulose, powdered cellulose, starch, pregelatinized starch, dextrates, dextran, dextrin, dextrose, maltodextrin, calcium carbonate, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulfate, magnesium carbonate, magnesium oxide, poloxamers such as polyethylene oxide, and hydroxypropyl methyl cellulose.

Examples of surface active agents include sodium lauryl sulfate and polysorbate 80.

Examples of drug complexing agents or solubilizers include the polyethylene glycols, caffeine, xanthene, gentisic acid and cylodextrins.

Examples of disintegrants include sodium starch glycolate, sodium carboxymethyl cellulose, calcium carboxymethyl cellulose, croscarmellose sodium, crospovidone (polyvinylpolypyrrolidone), methyl cellulose, microcrystalline cellulose, powdered cellulose, starch, pregelatinized starch, and sodium alginate.

Examples of tablet binders include acacia, alginic acid, carbomer, carboxymethyl cellulose sodium, dextrin, ethylcellulose, gelatin (also a preferred material for capsules obtainable from a method according to the fourth aspect or the twelfth aspect of the invention), guar gum, hydrogenatetd vegetable oil,

hydroxyethyl cellulose, hydroxypropyl cellulose (also a preferred material for capsules obtainable from a method according to the fourth aspect or the twelfth aspect of the invention), hydroxypropyl methyl cellulose, methyl cellulose, liquid glucose, maltodextrin, polymethacrylates, povidone, pregelatinized starch, sodium alginate, starch, sucrose, tragacanth, and zein.

Examples of lubricants include calcium stearate, glyceryl monostearate, glyceryl palmitostearate, hydrogenated vegetable oil, light mineral oil, magnesium stearate, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, sodium stearyl fumarate, stearic acid, talc, and zinc stearate.

Examples of glidants include silicon dioxide, talc and cornstarch.

Compositions of this invention may be used in a wide variety of dosage forms for administration of drugs. Exemplary dosage forms are powders or granules that may be taken orally either dry or reconstituted by addition of water to form a paste, slurry, suspension or solution; tablets; capsules; multiparticulates; and pills. Various additives may be mixed, ground, or granulated with the compositions of this invention to form a material suitable for the above dosage forms.

In some cases, the overall dosage form or powders (particles), granules or beads that make up the dosage form may have superior performance if coated with an enteric polymer to prevent or retard dissolution until the dosage form leaves the stomach. Exemplary enteric coating materials include HPMCAS, HPMCP, CAP, CAT, carboxymethylethyl cellulose, carboxylic acid-functionalized polymethacrylates, and carboxylic acid-functionalized polyacrylates.

Compositions of this invention may be administered in a controlled release dosage form. In one such dosage form, the composition is incorporated into an erodible polymeric matrix device. By an erodible matrix is meant aqueous-erodible or water-swellable or aqueous-soluble in the sense of being either erodible or swellable or dissolvable in pure water or requiring the presence of an acid or base to ionize the polymeric matrix sufficiently to cause erosion or dissolution. When contacted with the aqueous environment of use, the erodible polymeric matrix imbibes water and forms an aqueous-swollen gel or "matrix" that entraps the composition. The aqueous-swollen matrix gradually erodes, swells, disintegrates or dissolves in the environment of use, thereby controlling the release of the drug mixture to the environment of use.

Alternatively, the compositions of the present invention may be administered by or incorporated into a non-erodible matrix device.

In addition to the above additives or excipients, use of any conventional materials and procedures for preparation of suitable dosage forms using the compositions of this invention known by those skilled in the art are potentially useful.

The kit according to a twenty-third aspect of the

invention, may comprise the weak acidic liquid in a vial or bottle (preferably vinegar or acetic acid) and the container according to the eighth aspect in the form of a stick. The bottle/vial together with stick may be comprised in a box. Said box may further contain several bottles/vials and sticks.

In addition to the fact that the composition according to the first aspect of the invention is more nature friendly as set out earlier above, it has a better quality and is a cleaner product.

Preferred features of each aspect of the invention are as for each of the other aspects mutatis mutandis. The prior art documents mentioned herein are incorporated to the fullest extent permitted by law. The invention is further described in the following examples in conjunction with the appended drawings, which do not limit the scope of the invention in any way. Embodiments of the present invention are described in more detail with the aid of examples of embodiments, the only purpose of which is to illustrate the invention and are in no way intended to limit its extent.

Brief Description of the Drawings

Figure 1 is a schematic drawing of the manufacture of the edible minus hydrogen powder

Figure 2 is a schematic drawing of the manufacture of the hydrogenated magnesium.

Figure 3 is a schematic drawing of the manufacture of the hydrogen balance capsule and tablet.

Figure 4 is a schematic drawing of the manufacture of the metal magnesium hydrogen ion capsule and tablet.

Figure 5 is a schematic drawing of the manufacture of the magnetic ceramic ball.

Figure 6 is a schematic drawing of the manufacture of the hydrogenated calcium powder for use when making hydrogen plasma water.

Figure 7 is a schematic drawing of the preparation of a hydrogen plasma water.

Figure 8 is a further schematic drawing of the preparation of a hydrogen plasma water.

Figure 9 is a schematic drawing of the preparation of a stick for providing a hydrogen plasma water.

Figure 10 is a schematic drawing of the method in example 10.

Figure 11 shows changes in triglyceride levels.

Figure 12 shows changes in LDL-cholesterol levels.

Figure 13 shows changes in HDL-cholesterol levels.

Figure 14 shows changes in ((TC-HDL)/HDL).

Figure 15 shows changes in weight.

Figure 16 shows study design.

Figure 17 shows clinical examination.

Figure 18 shows overview of hormones.

Figure 19 shows changes in estradiol.

Figure 20 shows changes in ACTH.

Figure 21 shows changes in cortisol.

Figure 22 shows changes in adrenaline.

Figure 23 shows changes in noradrenaline.

Figure 24 shows the material used in example 11.

Figure 25 shows analysis of hydrogen.

Figure 26 shows method of analysis of hydrogen.

Figure 27 shows changes in TG.

Figure 28 shows changes in TC (total cholesterol).

Figure 29 shows changes in fasting LDL cholesterol.

Figure 30 shows changes in fasting HDL cholesterol.

Figure 31 shows changes in ((TC-HDL)/HDL).

Figure 32 shows changes in HDL /HDL ratio.

Figure 33 shows changes in body weight.

Figure 34 and 35 show changes in fat.

Figure 36 shows method of analysis of hydrogen.

Figure 37 shows the case in example 12.

Figure 38 shows also the case in example 12.

Figure 39 shows also the case in example 13 – before treatment.

Figure 40 shows also the case in example 13 – after treatment.

EXAMPLES

Example 1 - manufacturing of edible minus hydrogen ion powder production process (c.f. JP 4404657 (JP200458446A)); also reflected in Figure 1

Material

Fossil coral calcium from Okinawa

Manufacturer: corals Bio-tech Co. Ltd

Product name: a food additives, corals uncalcined calcium

Trade name: Coral Bio- PW® (herein after PW)

Kneading and formation

- Add 5.7 litter pure water to raw material PW (20kg per bag).

It mixes for 2.5 minutes by the exclusive mixer (initial stir for 30 seconds to main churning for 2 minutes).

- Form round the materials which kneaded and went up in the shape of a rice cakes at around (they are about 60 pieces with 20kg of materials) about 400g per piece. (popular name: Dumpling)

Dryness

- According to a formation process, cover woven wire dryer only with a kitchen paper for the formed dumpling, and carry about 20 dumplings to one wire.
- Put into an exclusive drier and switch on a drier.

Drying times will be dried from a dryer operations commence for 18 hours or more on about the 1 day (overnight).

- By a case, when dryness is insufficient, extend drying times.

Oxidation calcination

- Pick out the dry dumpling from a drying machines according to a dryness process.
- Laid with a furnace plate in an oxidization calcination machine (electric furnace), and accumulate the dumpling dried to the furnace plate.
- Switch on and calcinate the power supply of an oxidation calcination machine.
- Calcinate with the calcination temperature 720 degree C for 8 hours.
- Reach 720 degree C in after 4 hours at the time of a calcination start, maintain 720 degree C after that, and calcinate for 4 hours.
- Carry out natural cooling of it in the state as it is until after calcination becomes room temperature (temperature which touches by hand).
- When picking out a dumpling from an oxides furnace, according to a difference of temperature (particularly winter season) with outside temperature, or the condition of an oxidation furnace, when there is a dumpling of black color or gray color with imperfect oxidized calcination, take independently, place, and perform the above-mentioned oxidation calcination process again. (2 times baking)

Reduction calcination

- Stuff into sagger container the dumpling which carried out oxidation calcination according to an oxidation calcination process.
- Use eight sagger containers to reduction furnace machine 1 set.
- Put about 2kg (per sagger container) in six pieces among eight sagger container at two about 4kg (per sagger container). (the sagger containing about 4kg is placed as the upper stage, and it puts into four steps at 2 sequence pile in the inner part of a reduction calcination machine.)
- Put in about 100kg (it is a maximum of 120kg by the current work method) of reduction calcination machine about 20kg per set (it is a maximum of 24kg by current work method) five-set sum totals.

- Put in a heat shield plate and shut lid of reduction furnace tightly.

- Change the in-pile into vacuum conditions of the atmosphere for a reduction calcination machine based on a moving procedure, pass the hydrogen gas and nitrogen gas mixture, and calcinate by 650 degree C in this mixed gas for long hours.

(From a firing started, 650 degree C is reached in 2 hours, and 4-hour 650 degree C is maintained and calcinated henceforth. Supplying gas is continued although a heater is turned off on a program at this time (6 hours). Bake by preheat continues before or after about 11 hours until it pulls out a muffle furnace.

- Pull out an after reduction firing muffle furnace, and switch on and carry out natural cooling of the power supply of the ventilation duct for natural cooling. Since gas supply may surcease, oxygen in the atmosphere may mix and oxidization calcination of the temperature condition materials may still be carried out if powers of reduction furnace are derogated at this time, a power is not derogated, but stops only flow of hydrogen gas, and pouring nitrogen gas is continued.

- Stop powers of reduction furnace and gas several hours after (about 4 hours after), and take out the materials (sagger container) which carried out reduction calcination. At this time, natural cooling is carried out until it becomes room temperature (temperature of the grade touched by hand), since it is still in a high temperature state.

- Feed materials into special buckets for every reduction calcination machine, and dispatch to the pulverization room of the through clean room A at pass box.

Rough pulverization and this pulverization

- Cover the materials by which reduction calcination was carried out over a pre-milling machine for every reduction calcination machine.

After rough pulverization, a sample is taken out for every reduction calcination machine, and quality testing (redox concentrations and the value of pH measurement) is conducted.

- For every reduction calcination machine, feed into this grinder only the materials which passed quality inspection, and they carry out actual pulverization.

- Take out a sample for every reduction calcination machine after this pulverization, and conduct the final quality testing (redox potential concentrations and the pH value measurement). Send only the minus hydrogen ion powder which passed the last quality inspection to a through product room at pass box.

Inspection and packaging (product room)

- Before packing the minus hydrogen ion powder which actual pulverization was carried out and passed the final quality testing, there is no foreign substances etc., or conduct visual inspections.

- Pack in a lamizip containers etc. according to a use. Under the present circumstances, it packs for every reduction firing machine, and a fraction is mixed as a mix article. Since a mix article may depend from the quality data of each reduction furnace, it takes out a sample and conducts the last inspection of quality as a mix article.
- Apply to a metal tester for every packed product, and there is no metaled (foreign body) contamination, or conduct the final inspection.

Filling and goods setup (a filling room and a packaging room)

- When there is order with capsule goods, dispatch to a filling room through the products that pass the final inspection (packaged goods) at pass box.
- Perform encapsulation using an encapsulation machine.
- The capsule by which capsule filling was carried out sends pass box to a through packaging rooms.
- Set up each product and manufacture products at a packing room.

Packaging

- Send each product manufactured at the product for materials shipment packed at the product room, and the packaging room to a through packaging room at pass box.
- Pack up a product or goods with a packaging room to cardboard etc.

Storage and shipments

- Ship the products packed up with the packaging room.
- When not shipped soon, move to a product preservation warehouse and keep it.
- In a product storage warehouse, control the quality so that temperature management may be performed (in particular summer) and deterioration of quality may not start.

Example 2 - manufacturing of hydrogenated magnesium

; also reflected in Figure 2

Material

- Magnesium oxides which used the domestic sea mineral (seawater) as main raw material

Product name: Magnesium oxides

Trade name: SAMMAGU Kyowa (herein after called SAMMAGU)

Manufacturer: Kyowa Hakko Co., bio Ltd

When two or more magnesium oxide of a maker was compared, there was no difference in the component itself much, but since the redox potential after reduction calcination and the value of pH were excellent, it was adopted.

Kneading and forms and drying and oxidation calcination

Above processes is nothing.

Reduction calcination

- Pack SAMMAGU to sagger container with material powders.
- As the volume of material powder is too large, the powder of about 1 kg was stuffed into one sagger container.
- Put in reduction machine calcination machine eight sagger container (about 8kg) per set.
- Put in the heat shield plate and shut the lid of a reduction calcination machine firmly.
- Change the in-pile into vacuum conditions of the atmosphere for a reduction furnace machine based on a moving procedure, pass the hydrogen gas and nitrogen gas mixture, and calcinate by 650 degree C in this mixed gas for long hours.

(From a calcination started, 650 degree C is reached in 2 hours, and 4-hour 650degree C is maintained and calcinated henceforth. Supplying gas is continued although a heater is turned off on a program at this time (6 hours). Bake by preheat continues before or after about 11 hours until it pulls out a muffle furnace.

- Pull out an after reduction firing muffle furnace, and switch on and carry out natural cooling of the power supply of the ventilation duct for natural cooling. Since gas supply may surcease, oxygen in the atmosphere may mix and oxidization calcination of the temperature condition materials may still be carried out if powers of reduction bagel toasters is derogated at this time, a power is not derogated, but stops only flow of hydrogen gas, and pouring nitrogen gas is continued.
- Stop powers of reduction furnace and gas several hours after (about 4 hours after), and take out the materials (sagger container) which carried out reduction calcination. At this time, natural cooling is carried out until it becomes room temperature (temperature of the grade touched by hand), since it is still in a high temperature state.
- The materials into special buckets for every reduction calcination machine, and dispatch to the pulverization room of the through clean room A at pass box. (Since a specific gravity is mild, each work is done carefully)

Rough pulverization and this pulverization

- a milling process also has no materials after calcination because of a powder form.
- since there is no pulverization process at this time -- a sample taking out (redox concentrations and measurement of the value of pH) carried out.

Inspection and packaging (product room)

- Before packing the reduced magnesium (reduction SAMMAGU) which passed the final quality inspection, there is no foreign substances etc., or conduct visual inspections.
- Pack in a Lamizip containers etc. according to a use. Under the present circumstances, it packs for every reduction furnace machine, and a fraction is mixed as a mix article. Since a mix article may depend from the quality data of each reduction furnace, it takes out a sample and conducts the final inspection of quality as a mix article.
- Apply to a metal tester for every packed product, and there is no metaled (foreign body) contamination, or conduct the final inspection.

Storage

- The packed hydrogenated magnesium moves to a product preservation warehouse, and keep it.
- In a product storage warehouse, the quality control so that temperature control may be performed (in particular summer) and deterioration of quality may not start.

Example 3 - manufacturing of hydrogen balance; also reflected in Figure 3

Material

Edible minus hydrogen ion® powder (as set out in example 1 above)

Hydrogenated Magnesium (reduction SAMMAGU) (as set out in example 2 above)

Mixing

• 1) Send pass box for the materials of ① and ②. to the product room of the through clean room A from a product preservation warehouse.

2) Since the specific gravity of ①and② is different, perform mixed churning in each 2 kg, respectively

The amount of 2 kg combination

Edible minus hydrogen ion® powder: 1,544.2g

Hydrogenated Magnesium (reduction SAMMAGU): 455.8g

(Being a containing components ratio after mixture: Calcium 2: Magnesium 1 ratio)

- Put after mixed churning into a lamizip containers etc., and pack it.

- When storage, each 2kg, put into a Lamizip containers, pack, and storage in a product preservation warehouse. (herein after called to: hydrogen balance powder)
- When carrying out capsule filling, dispatch pass box to a through filling room.

Encapsulation

- Do fill operation for the mixed hydrogen balance powder on a HPMC Green capsule (No. 2 capsule green color).

* Excel in the soluble in internals compared with the HPMC capsules (capsule which used plant-pulp-origins ingredients hydroxypropyl methylcellulose) existing capsule material, and excel that ingredients in capsules deteriorates and cannot oxidize easily.

Tablet preparation (tablet form)

- For the tablet preparation, the hydrogen balance powder or edible minus hydrogen ion powder and hydrogenated magnesium are dispatched to a contract processor, and then are making at there.

Product set up

- The tablet and capsule products were manufactured by an ordering situation,
- Then pack in each container.(A bottle, a plastics bottle and ramijip container, etc.)
- Carry out box stuffing of the goods of a bottle container individually, and they perform shrink films processing after a seals approval seal.
- Conduct metal inspection after the end of a setup.
- Send the completed products to a packaging room through Path BOX.

Packaging

Products are packed up and shipped to a cardboard boxes etc.

Example 4 - manufacturing of magnesium metal combined with hydrogen ion balance; also reflected in Figure 4

Material

Edible minus hydrogen ion® powder (see example 1)

Magnesium metal (98% of degree of purity magnesium)

Product name: a reagent, magnesium powder, the 1st grade

Manufacturer: Kanto Kagaku Inc. (2)

Mixing

Edible minus hydrogen ion powder and metal magnesium are sent to the product room of the clean room A from a product preservation warehouse with pass box.

Loads for combination

Edible minus hydrogen ions® powder, 2000g

Metal magnesium 363g

- Perform mixed churning in the above-mentioned amount of combination.
- Put after mixed churning into a Lamizip containers etc., and pack it.
- When storage, every 2363g, put into a Lamizip containers, pack, and storage in a product preservation warehouse. (herein after called: metal Magnesium hydrogen powder
- When carrying out capsule filling, dispatch pass box to a through filling room.

Encapsulation

- Do fill operation for the mixed metal Magnesium hydrogen powder on a gelatins pink capsule (No. 2 capsule pink).

* Since magnesium metal tends to be caught in a capsule connection, it is easy to come out of a Lo.

* gelatin capsule (capsule which used porcine origin gelatin)

Tablet making (tablet form)

- tablet making machine sends metal magnesium hydrogen powder or edible minus hydrogen ion powder and metal magnesium to a contract processor, and then they are making it there.

Packing/delivery

- Pack and ship to a Lamizip containers etc. for future shipment.

Example 5 - manufacturing of magnetic ceramic balls; also reflected in Figure 5 (c.f. JP2002382862A (JP 4218939))

Material

1)Fossil coral calcium from Okinawa Prefecture

product name: a food additives, corals uncalcinated calcium trade name: The Coral Bio-PW® (herein after PW)

Manufacturer: corals biotech Co. Ltd

2) Milo-necton

Product name: Milo-necton

Trade name: raw materials for cosmetics

Manufacturer: Dai-Nippon Kasei Chemical Co., Ltd.

3) Zeolite

Product name: Zeolite

Trade name: Nitto zeolite

Manufacturer: Nitto powdering chemical industrial Co., Ltd

4) Iron oxides (95%, pure Fe2O3)

Product name: a reagent, iron oxides Ist grade

Manufacturer: Kanto Kagaku Inc.

Mixing

Minimum mixed quantity: 200g

PW : 48g

Milo-necton : 53.2g

Zeolite : 88.8g

Iron oxides : 10g

- Blend by the above-mentioned combination ratio and perform agitation mixture.
- Agitate churning mixture firmly until the whole becomes a color (cinnabar color) of iron oxide.

Kneading

- In the materials which carried out churning mixture, pure water is added small quantity every and agitated, and it is kneaded and crowded until it becomes the stiffness suitable for form.
- In the stage of kneading, perform kneading carefully until the whole color becomes uniform.

Forms

- Form carefully one by one in the shape of 10mm in diameter a magnitude a sphere (a magnitude changes with purposes of use separately). (herein after called: a ceramic balls)

Dryness

- Put the formed ceramic balls into the cooking sheets processed in the shape of a plate, and put on woven wire dryer only.
- Put into an exclusive drier and switch on a drier.

Drying times will be dried from a dryer operations commence for 18 hours or more on about the 1 day (overnight).

- By a case, when dryness is insufficient, extend drying times.

Oxidation calcination

- Put the dry ceramic ball into sagger container only for ceramic balls.
- Switch on and calcinate the power supply of an oxidization calcination machine.
- Calcinate with the calcination temperature 720 degree C for 8 hours.
- Start without preheat, and after that to 720 degree C attainment for 4 hours and maintain 720 degree C attainment for 4 hours, and then calcinations achieved.
- Carry out natural cooling of it in the state as it is until after calcination becomes room temperature (temperature which touches by hand).

Reduction calcination

- Reduction calcination of ceramic balls does not use heating-proof containers, such as sagger container, in the furnace of a reduction calcination machine, but throws in directly the ceramic ball which carried out oxide calcination. - the color of the ceramic ball in this time -- auburn.
- The amount supplied to reduction furnace machine 1 set supplies 6kg or less to a standard. (A maximum of 6 to 7 kg)
- Put in a heat shield plate and shut lid of reduction furnace tightly.
- Change the in-pile into vacuum conditions of the atmosphere for a reduction calcination machine based on a moving procedures, flow the hydrogen gas and nitrogen gas mixture, and calcinate by 650 degree C in this mixed gas for long hours. (From a calcination started, 650 degree C is reached in 2 hours, and 4-hour 650 degree C is maintained and calcinated herein after. Supplying gas is continued although a heater is turned off on a program at this time (6 hours). Bake by preheat continues before or after about 11 hours until it pulls out a muffle furnace.)
- Pull out muffle furnace after reduction calcination, and switch on and carry out natural cooling of the power supply of the ventilation duct for natural cooling. Since gas supply may surcease, oxygen in the atmosphere may mix and oxidization calcination of temperature condition ceramic balls may still be carried out if powers

of reduction furnace are derogated at this time, a power is not derogated, but stops only flow of hydrogen gas, and pouring nitrogen gas is continued. (When oxidation calcination occurs, colors of ceramic balls changes to reddish brown, blackish brown, white gray, etc., and colors of ceramic balls becomes sparse)

- Stop powers of reduction furnace and gas in several hours (about 4 hours after), and take out the ceramic balls which carried out reduction calcination. At this time, natural cooling is carried out until it becomes room temperature (temperature of the grade touched by hand), since it is still in a high temperature state.
- As for colors of ceramic balls, the whole becomes black grey if oxidation reaction is not coming.
- Take out the ceramic balls by which reduction calcination was carried out to a plastic bags etc.

Magnetization

- The ceramic ball which carried out reduction calcinations is taken with magnetism irradiation, using a magnetization machine.
- Radiation time: 2 T gauss 5-second interval radiation for five times

Product quality test

- Conduct quality inspection (Redox potential and pH value measurement) of a ceramic ball which carried out magnetization.

Packaging

- Only the ceramic ball which passed quality inspection test moves to a packing room, and pack it to a Lamizip containers etc. for every reduction calcination machine.

Storage

- Move to a product depot and keep the packed ceramic balls.
- In a product storage warehouse, control the quality so that temperature management may be performed (in particular Summer) and deterioration of quality may not start.

Example 6 - manufacturing of hydrogenated calcium; also reflected in Figure 6 (c.f. JP2002382862A (JP 4218939))

Material

Calcium carbonate

Product name: Calcium carbonate

Trade name: a food additive, Mamakaruso

Manufacturer: Nitto Powdering Industrial Co. Ltd

Kneading, formation, and dryness

Since it is processed with the shape of powder, no above mentioned process

Oxidation Calcination

- Pack calcium carbonate (Mamakaruso) to sagger container with material powders.

(They are about about 1.5 - 2kg to one sagger container)

- Put in one to three sagger container which packed materials to the oxidation calcination machine 1 set.
- Switch on and calcinate the power supply of an oxidization calcination machine.
- Calcinate in calcination temperature 720 degrees C for 8 hours.
- Start without preheat, and maintain 720 degree C attainment for 4 hours and after that maintained at 720 degree C for 4 hours and then be achieved with calcination.
- Carry out natural cooling of it in the state as it is until after calcination becomes room temperature (temperature which touches by hand).

Reduction calcination

- In reduction calcination machine, eight sagger container (about 10 - 15kg) set put in.
- Put in a heat shield plate and shut the lid of a reduction furnace machine firmly.
- Change the in-pile into a vacuum conditions of the atmosphere for a reduction firing machine based on a moving procedures, flow the hydrogen gas and nitrogen gas mixture, and calcinate by 650 degree C in this mixed gas for a long.

(From a firing started, 650 degree C is reached in 2 hours, and 4-hour 650 degree C is maintained and calcinated herein after. Supplying gas is continued although a heater is turned off on a program at this time (6 hours). Bake by preheat continues before or after about 11 hours until it pulls out a muffle furnace.

- Pull out muffle furnace after reduction calcination and switch on and carry out natural cooling of the power supply of the ventilation duct for natural cooling. If powers of reduction furnace are derogated at this time, since gas supply may surcease, the oxygen in the atmosphere may mix and oxidization calcination of the temperature condition materials may still be carried out, a power is not derogated, but stops only flow of hydrogen gas, and pouring nitrogen gas is continued.
- Stop powers of reduction furnace and gas several hours after (about 4 hours after), and take out the materials (sagger container) which carried out reduction calcination. At this time, natural cooling is carried out until it becomes room temperature (temperature of the grade touched by hand), since it is still in a high temperature state.
- Feed materials into special buckets for every reduction furnace, and dispatch to the pulverization room of the through clean room A at pass box.

Rough pulverization and this pulverization

- A milling process also has no materials after calcination because of a powder form.
- Since there is no pulverization process at this time and then a sample is taking out (the redox potential concentrations and the pH value measurement) is carried out.

* Although the calcium carbonate after reduction calcination is state of powder, some solid state is recognized, and in the use (for example: such as food supplement and etc.) of those other than the materials of hydrogen water, it is important point examination about this pulverization.

Inspection and packaging (product room)

- Before packing the reduced calcium carbonate which passed the last quality test, there is no foreign substances etc., or conduct visual inspections.
- Pack in a Lamizip containers etc. according to a use. Under the present circumstances, it packs for every reduction furnace, and a fraction is mixed as a mix article. Since a mix article may depend from the quality data of each reduction furnace, it takes out a sample and conducts the last quality inspection as a mix article.
- Apply to a metal tester for every packed product, and there is no metaled (foreign body) contamination, or conduct the final inspection.

storage

- The packed calcium hydride moves to a product storage warehouse, and keep it.
- In a product storage warehouse, control the quality so that temperature management may be performed (in particular summer) and deterioration of quality may not start.

Example 7 - manufacturing of hydrogen plasma water; also reflected in Figure 7 –powder filtration good

Material

Hydrogenated Magnesium (reduction SAMMAGU)

Hydrogenated Calcium

Rock salt

Trade name: Crystal salt

Manufacturer: Rapisu JAPAN Co.

Load (20 liters for manufacture)

Hydrogenated Magnesium: 41g

Hydrogenated Calcium: 20.5g

Rock salt: 18g

Preparation

- Put 20 liters of drinking water into the 20 liter polybottle for drinking water.
- Pay three sorts of blended materials, shut a cover tightly and agitate it.

Filtration and packaging

- Since a redox potentials and pH value are not stabilized immediately after preparation churning, it is preferred to do filtration process after at least 3 hours after the preparation work.
- Filter in the present work preparation and on the next day on the previous day.
- Prepare a short form 2 connection barrier filter.
- Agitate once again just before filtration. (a redox potentials becomes good by filtering, after agitating precipitating materials)
- Operate the pump for simple filter filters and start filtration process.
- Check a filtration state (transparence), extract samples for quality specimens, and conduct quality testing (redox potentials and pH value measurements). (According to production volume, sample collection is performed several times)
- Pump up in 20 liters. (container for shipment) of containers only for hydrogen water.
- The water which shut the lid tightly and adhered fully container after 20 liters dipping up has been wiped.
- Pack up in a carton box.

Shipments

Since quality testing and productions become concurrent, only the with hydrogen waters plasmas® which passed quality testing is shipped.

Example 8 - manufacturing of hydrogen plasma water using stick embodiment; also reflected in Figure 8

Material

The stick for hydrogen plasma waters® preparation

The stick containing a magnetic ceramic ball (herein after the stick for hydrogen plasma waters®preparation) which possesses the reduction property is used (see example 5).

Preparation cleaning

- Immence advantage of vinegar for 60 seconds, and rinse firmly the stick for hydrogen plasma water® preparation with tap water shortly after.

Preparation

- Put 20 liters of drinking water into 20 liters (container for shipment) of containers only for drinking water.
- Insert 20 washed sticks for with hydrogen plasma waters® preparation. (It is one to one liter)
- By the present work, they are preparation the previous day and then shipping on the next day. You can also leave water to rest during 3 days.

(Since hydrogen plasma water® is not completed for a short time)

Productions and packaging

- Extract the stick for with hydrogen plasma waters® preparation from a 20 liter container after making it passed for three days more.
- From each container, extract samples for quality specimens and conduct inspection of quality.
- The part which measures only the with hydrogen plasma waters® which passed inspection of quality and by which it is less than 20 liters adds the with hydrogen plasma waters® which taught too much and passed inspection of quality.
- The water which shut the lid tightly and adhered fully container has been wiped.
- Pack up in a carton box.

Shipments

Finished products are shipped.

Example 9 - manufacturing of stick embodiment used for hydrogen plasma water in example 8; also reflected in Figure 9

Material

The magnetics ceramic balls

Metal Magnesium (pure magnesium)

Manufacturer: Tokyo Magnesium Co.

Activated carbon: (for food manufacture processing water and drinking water)

Product name: Coconut activated carbon
Manufacturer : C S laboratory Co.Inc.

Wrapper material
Polyester mesh (25 mm x 140mm suture)
Manufacturer : C S laboratory Co. Inc.

Loads
The Magnetics Ceramic Balls : 3g
Magnesium : 2g of 0.7φx2φ grains
Magnesium : 1.5g of 3φx6φ grains
Magnesium: 1.5g of facet-like 1.5g
Activated carbon : 5g

Manufacturing method

- Carry out sewing of the container (wrapper material) to which materials are paid to saccate (25mm x 140mm) employing a polyester mesh fabric.

• Materials of the magnetic ceramic balls, metal magnesium and Activated carbon put in so that the whole may become uniform into wrapper material, and suture an entrance.

* Creation is requested from an outside contractor in handmade fashion.

Example 10 - hyperlipemia

The effect of Minus Hydrogen Supplements on Hyperlipemia

10 patients:
The patients were diagnosed as hyperlipemic by medical diagnosis during 2006~2007. All patients then consumed minus hydrogen supplements and follow up tests were confirmed.
Ages: 42 to 77
Gender: 5 male, 5 Female
The blood samples performed all double checked. Starting by confirming the initial values from the medical test results, the test was subsequently performed double checks on each of the fasting blood tests done at 6 to 10 weeks and again at 14 to 20 weeks following the commencement of minus hydrogen supplement consumption.

Statistical analysis

Using the Stat Mate III program, the test were checked for any significant data using a repetition measure variance analysis approach and compared results between groups with multiple comparisons.

Table 1

Cases

	Age:Sex	Disease	Medication	A1c change*
1.	51F	hyperlipemia, diabetes	none	A1c 6.4 → 5.7
2.	58F	hyperlipemia, diabetes	antidiabetic agent	A1c 10.4 → 8.7
3.	48F	hyperlipemia, hypertension	none	
4.	70F	hyperlipemia, diabetes, hypertension	antihypertensive agent	A1c 6.6 → 6.3
5.	42F	hyperlipemia	none	
6.	77M	hyperlipemia, diabetes, hypertension	antihypertensive and antidiabetic agent	A1c 6.6 → 6.3
7.	50M	hyperlipemia	none	
8.	52M	hyperlipemia, diabetes, angina	antidiabetic agent and medication for angina	A1c 8.7 → 6.7
9.	47M	hyperlipemia	none	
10.	59M	hyperlipemia, diabetes, hypertension	antihypertensive and antidiabetic agent	A1c 7.4 → 7.0

*The changes of A1c indicates the changes between the previous values and the values after taking hydrogen.

Conclusion

Triglyceride levels went down significantly 2 months after diet guidance began. However, by 4 months there were no further reductions and normal triglyceride levels were not reached. After adding the hydrogen supplements these levels went down significantly with normal triglyceride levels being reached and maintained.

No significant changes were observed in total cholesterol, LDL and HDL levels after diet guidance and hydrogen supplementation.

The arteriosclerosis index (normal level = 3 or under) was clearly high in each of the patients. No improvement was observed by dieting. Following hydrogen supplementation there were significant declines with patients coming in near to the normal range.

The patients' weight declined significantly under diet guidance but went down significantly more following hydrogen supplementation.

Remarks on observations

Hydrogen seemed to contribute to significant reductions in triglycerides and weight. Since there were also improvements in blood sugar A1c among diabetic patients, hydrogen may have enabled greater energy metabolism, which is further supported by hydrogen's apparent synergistic effect with diet. (In fact, there were some cases where patient's blood sugar level, triglyceride level and weight increased among those who took only hydrogen supplements without diet.)

Total cholesterol and LDL cholesterol decreased and HDL cholesterol levels increased in those taking hydrogen supplements but not to a significant degree. This study observed that overall, hydrogen supplements induced a positive effect on cholesterol, which follows a different metabolic pathway than triglycerides and sugar. Hydrogen may lead to the possibility of improvements in arteriosclerosis.

Table 2

TC		pre		edu		hyd	
		previous values		after diet education		hydrogen supplementation	
Patient		pre1	pre2	edu1	edu2	hyd1	hyd2
1	TC	207	251	233	246	203	202
2	TC	210	204	204	208	197	204
3	TC	334	305	291	288	224	238
4	TC	321	324	309	265	264	264
5	TC	221	189	198	195	222	188
6	TC	227	231	220	208	200	197
7	TC	190	224	192	205	235	191
8	TC	192	198	190	181	186	179
9	TC	235	224	245	218	221	232
10	TC	275	263	266	287	253	283
	avr	241	241	235	230	221	218
	sd	52	45	42	39	25	35
	SE	16.3	14.2	13.4	12.2	7.9	11.0

TG		pre		edu		hyd	
		previous values		after diet education		hydrogen supplementation	
Patient		pre1	pre2	edu1	edu2	hyd1	hyd2
1	TG	204	238	154	161	139	140
2	TG	217	241	169	176	127	123
3	TG	348	243	202	200	84	94
4	TG	364	354	257	272	189	172
5	TG	295	213	195	192	182	141
6	TG	200	234	189	176	164	198
7	TG	150	156	115	114	108	109
8	TG	307	340	249	302	168	181
9	TG	236	201	143	173	84	114
10	TG	319	224	205	186	166	198
	avr	264	244	188	195	141	147
	sd	72	60	45	54	39	38
	SE	22.8	19.0	14.1	17.1	12.3	12.0

Table3

Table 4

HDLC		pre		edu		hyd	
		previous values		after diet education		hydrogen supplementation	
Patient		pre1	pre2	edu1	edu2	hyd1	hyd2
1	HDLC	51	66	52	51	53	52
2	HDLC	39	44	40	41	44	45
3	HDLC	45	43	44	46	45	45
4	HDLC	43	45	44	46	52	50
5	HDLC	51	53	57	62	63	59
6	HDLC	63	60	58	56	58	58
7	HDLC	48	50	48	50	57	54
8	HDLC	52	49	50	51	52	51
9	HDLC	72	68	72	61	66	66
10	HDLC	46	50	53	53	56	53
	avr	51	53	52	52	55	53
	sd	10	9	9	7	7	6
	SE	3.1	2.8	2.9	2.1	2.2	2.0

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Table 5

LDLC		pre		edu		hyd	
		previous values		after diet education		hydrogen supplementation	
Patient		pre1	pre2	edu1	edu2	hyd1	hyd2
1	LDLC	115	137	150	165	130	122
2	LDLC	132	112	130	132	128	138
3	LDLC	219	213	207	202	162	174
4	LDLC	205	208	214	165	174	180
5	LDLC	121	93	102	95	123	99
6	LDLC	124	124	124	117	109	99
7	LDLC	112	143	121	132	156	115
8	LDLC	79	81	90	96	100	78
9	LDLC	116	116	144	122	138	143
10	LDLC	165	168	172	197	164	190
	avr	139	140	145	142	138	134
	sd	44	45	41	38	25	38
	SE	13.9	14.2	13.1	12.1	7.8	12.0

Table 6

BW		pre	edu	hyd
		previous values	after diet education	hydrogen supplementation
Patient		pre1	edu1	hyd1
1	BW	74	73	72
2	BW	85	82	82
3	BW	57	56	52
4	BW	68	65	63
5	BW	89	89	87
6	BW	78	76	72
7	BW	63	62	60
8	BW	80	79	79.4
9	BW	58	57.7	52
10	BW	46	45	45
	avr	69.8	68.5	66.4
	sd	13.8	13.6	14.2
	SE	4.4	4.3	4.5

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Table 7

ASI		pre		edu		hyd	
		previous values		after diet education		hydrogen supplementation	
Patient		pre1	pre2	edu1	edu2	hyd1	hyd2
1	ASI	3.06	2.80	3.48	3.82	2.83	2.88
2	ASI	4.38	3.64	4.10	4.07	3.48	3.53
3	ASI	6.42	6.09	5.61	5.26	3.98	4.29
4	ASI	6.47	6.20	6.02	4.76	4.08	4.28
5	ASI	3.3	2.57	2.47	2.15	2.52	2.19
6	ASI	2.6	2.85	2.79	2.71	2.45	2.40
7	ASI	2.96	3.48	3.00	3.10	3.12	2.54
8	ASI	2.69	3.04	2.80	2.55	2.58	2.51
9	ASI	2.26	2.29	2.40	2.57	2.35	2.52
10	ASI	4.98	4.26	4.02	4.42	3.52	4.34
	avr	3.92	3.72	3.67	3.54	3.09	3.15
	sd	1.57	1.40	1.28	1.07	0.64	0.38
	SE	0.50	0.44	0.40	0.34	0.20	0.28

See also figures 10-15.

Example 11 - hormonal secretion

A minus hydrogen ion research project - The clinical investigation on hormonal secretion - Open Study on 12-week consumption trial.

Purposes The Clinical investigation was performance for the purpose of verification of relevance between minus hydrogen ion supplement and hormone secretions

The method

Targets

20 or more years old and less than 50 years old

- Male healthy volunteers (5 professional athletes)(mean ages: 35 years old)
- Female healthy volunteers (11 professional athletes) (mean ages:23 years old)

Designs

A study on participants based on 1 capsule intake for a minus hydrogen ions capsules for one day. Two capsules are taken in before exercise. The amount change of hormonal secretion before and behind 1-hour exercise load was considered as an uncontrolled opening study.

The check of subjective symptoms, body measurement, and the blood test before and behind exercise load, and blood pressure and pulse measurement were enforced before a study and four weeks of test starts, and 12 weeks afterward. To the study participants, it investigated about the existence and the grade of the adverse experience. The study period was set to February 1, 2008-August 31, 2008. See also figure 16-18.

1) Estradiol (see figure 19)

The significant rise was together deemed four weeks and 12 weeks afterward by the woman.

Estradiol (estrogen) is one of the female hormone, and also has a cells regeneration (repair) function.

Growth rates

- Four weeks after: 169%
- 12 weeks after : 256%

A likelihood that the supplement has stimulated the gonadotrophic hormone of hypothalamus or the corpus luteum hormone (LH) of a hypophysis, and follicle- stimulating hormones (FSH) secretion can be considered.

3) corticotropin (ACTH) (see figure 20)

is a downward trend at a male, The significant rise was together deemed four weeks and 12 weeks after by the woman.

ACTH which is an index of stress also raises cortisol (see figure 21)

In a woman, cortisol goes up in 4 weeks, and it is "a phenomenon in which this is ordinary." Cortisol decreased and the "reverse phenomenon" occurred 12 weeks afterward. A potential that a supplement had "an anti- stress effects" by anti-oxidization and the anti-inflammatory effect was suggested.

4) catecholamines fractions"adrenergic" deemed the significant rise four weeks and 12 weeks afterward by the rise significant in four weeks, and the woman by the men. The "Noradrenaline" deemed the significant rise 12 weeks after by the woman.

Catecholamine is secreted from sympathetic nerves and adrenal medullas. Catecholamine goes up for movement, stress, etc. Increase in catecholamine, It becomes a factor important for an athlete. For Adrenaline see figure 22. For Noradrenaline see figure 23.

5) The other trends accepted by the Male Non
significant

6) The other trends acknowledged by the Female

Serotonin (zero week -> four weeks after: 2.6±20.3->14.6±11.5,
p= 0.)006

12 weeks after ->: With 2.5±16.6 and no significant difference

Dopamine (zero week -> four weeks after: with 0.00±0.01-
>0.00±0.01 and no significant
difference)

12 weeks after ->: -0.07±0.05, p=
0.001)

FT4 (zero week -> four weeks after: with 0.00±0.10 ->-0.05±0.10 and no significant difference)

12 weeks after ->: -0.14±0.10, p= 0.006)

About each clear association, it was unverifiable.

Physiological change etc. can be considered.

7) others evaluations Somatomedin C (IGF-I)DHEA-s Thyroid-stimulating hormones (TSH) Testosterone Free testosterone
FT3 CAMP receptor protein assay Lactate levels

The adverse experience critical during the study period was not acknowledged.

8) summary

1. corticotropin (ACTH) went up intentionally by the woman.
2. adrenergic went up intentionally by the male and the woman among catecholamine. Moreover, the Noradrenaline went up intentionally by the woman.
3. estradiol went up intentionally by the woman.
4. The event was not acknowledged.

From the above, the anti-oxidization action of a minus hydrogen ion supplement – and set particularly to a woman by the object from ATP for whole and raw fish with its meat cut in slices. A potential of being relevant to a "stress reaction system" and a "sex hormonal system" was suggested.

Example 12 - diabetes and hyperlipemia

The effect of a hydrogen preservation object on hyperlipemia

Introduction

Importance is attached to participation of the oxidization stress in various diseases. Activity is high, and specifically a hydroxyl radical has a short life, and since it is not qualitatively usual anti-oxidization enzyme or qualitatively / usual / of an anti-oxide eliminable, it is made high grade. It is reported that hydrogen gas eliminates a hydroxyl radical specifically in recent years.

On the other hand, the hydrogen preservation object (as a food supplement) of the solid which enclosed minus hydrogen ion as set out above was studied.

Purposes

By the following it was verified a generation of hydrogen gas from hydrogen preservation object, the clinical efficacy of minus hydrogen ion was performed over hyperlipemia diseases

Minus Hydrogen preservation object: see Figure 24

The manufacturing methods of a hydrogen storage body (hydrogen generations coral calcium)

1st process: the powdery coral calcium was carried out oxidative calcination at 950 °C in the atmosphere for 8 hours.

2nd process: the oxide calcined coral calcium was carried out reduction calcination at 950° C in mixed N_2 and H_2 (90%:10%) for 12 hours.

Verification of hydrogen gas generating from a hydrogen preservation objects

The measurement of hydrogen gas which is generated from a hydrogen preservation object (hydrogen gas generated when pure water is added in 1.0g of powered material) was analyzed with Gas chromatography in the Shimadzu General Analysis Center. The analysis was performed with 10 times.

Calibration of H_2: After glass bottle (volume of 1200ml) is filled with N_2 gas and then H_2 gas of 1.2ml be added and it mixed. The hydrogen gas level in the glass bottle at this time is set to 1000ppm. This gas was analyzed twice with gas chromatography (GC), H_2 peak was obtained, and the calibration factor of H2 was computed from that peak area.

Determination of Materials: Immediately after paying 1g of materials to glasses headspace vials with an amount of contents of 22ml, 10ml of pure water was added and the seal of the silicone rubber Teflon lining was carried out with an aluminum caps.

After shaking this vial, it was placed at room temperature, 0.5ml of gaseous phases of a container was collected with gas tight SHIRINJI, and it was analyzed with GC.

As a result of measuring over 3 days, it was from a hydrogen preservation object:

Hydrogen gas was generated and it reached before and after a mean of 800 ppm. See figure 25-Hydrogen emission measurement.

Objective

It applied in 2006 – 2007 and is a medical examination etc., Hyperlipidemia is pointed out and it is after confirmatory test, All patients took hydrogen preservation object.

Age: 42 years old - 77 years old

Gender: Male: 5 and Female:5

When hungry originally, it is a blood collecting view at the time of hungry for a blood collecting view and a check. It was considered as a last value,

It collects blood in 6 to 10 weeks, and 14 to 20 weeks after dietary guidance empty stomachs. Furthermore, it takes 1500~2000mg per day of a hydrogen preservation object and then Blood collecting is enforced in 6 to 10 weeks, and 14 to 20 weeks at the time of hungry. In the meantime, change was not added to the medicine which has on lipid and carbohydrate metabolism. See figure 26.

Statistic analysis

A Stat Mate III Program was employed; Factor repeated measures analysis of variance. It was authorized whether there is any their significance. It compared with a certain case each inter group by the multiple comparison.

Table 8

Patient Cases

	Age, Sex	Disease	Dose drug	Change of Alc*
1	51, F	Hyperlipidemia, Diabete	Nothing	Alc 6.4->5.7
2	58, F	Hyperlipidemia, Diabete	Antidiabetics	Alc 10.4->8.7
3	48, F	Hyperlipidemia, Hypertension	Nothing	
4	70, F	Hyperlipidemia, Diabete	Depressor	Alc 6.6->6.3
5	42, F	Hyperlipidemia	Nothing	
6	77, M	Hyperlipidemia, Diabete, Hypertension	Depressor, Antidiabetics	Alc 6.6->6.3
7	50, M	Hyperlipidemia	Nothing	
8	52, M	Hyperlipidemia, Diabete, Stenosis	Antidiabetics, Anti-stenosis	Alc 8.7->6.7
9	47, M	Hyperlipidemia	Nothing	
10	59, M	Hyperlipidemia, Diabete, Hypertension	Depressor, Antidiabetics	Alc 7.4->7.0

*: Change of Alc shows the change after a last value and hydrogen ingestion

See also figures 27-33.

LDLC=TC-HDLC-TG/5

If only TG falls without improving a cholesterol system LDLC should go up. There is no rise of LDLC in fact. The result which TC and HDLC have improved but only is seemed. See figure 33.

Height of 170cm / weight of 111kg

The example of the extreme overweight by which it is accompanied unusually the hormone/balance after a 40 years-old woman / infertility treatment

(normal weights: 63.6kg) The circumference navel waist / 130.5

commercial : BMI:38.41

See figures 34-35 and table 9 and 10 below:

Table 9

Change of Blood Sugar A1c in Diabete

Control State	Decrease	No change	Increase
Not Prescription -	4	2	1
Treatment with Oral -	Dose reduction and discontinuation 12	3	3
Insulin therapy IDDM	Dose reduction 3	-	-
NIDDM	Dose reduction and discontinuation 5	1	-
	24 (70%)	6	4

Total 34 patients

Table 10

Change of Blood Sugar A1c in Diabete

Control State	Decrease	No change	Increase
Not Prescription -	4	2	1
Treatment with Oral -	Dose reduction and discontinuation 12	3	3
Insulin therapy -	Dose reduction 3	-	-
NIDDM	Dose reduction and discontinuation 5	1	-
	24 (70%)	6	4

Total 34 patients

Summary

A generation of hydrogen gas was recognized for long time from hydrogen preservation object.

2. Although triglyceride fell intentionally 2 Months after dietary guidance. It does not fall even four months after and a normal ranges is arrived at It cut.

When hydrogen was added, it is owner mind also two months after. It fell, and the normal ranges were arrived at and it was maintained.

3. For total Cholesterol, LDL and HDL Cholesterol value, it does not significantly change even after dietary guidance and hydrogen consumption, It does not recognized a change significant also to a LDL/HDL ratio.

4. Body weight fell intentionally by dietary guidance. It fell still more nearly intentionally by hydrogen addition

Discussion 1

1. A neutral fat value and body weight fell intentionally by hydrogen preservation objects ingestion.

By the diabetic patient, since the improvement of the blood sugar level and A1c was also deemed, it was thought that this effect of hydrogen was brought about by improving the intracellular energy metabolisms, and it was thought that the effect was demonstrated more by having added dietary guidance.

2. A significant change was not deemed in total cholesterol and LDL cholesterol and HDL cholesterol level by hydrogen preservation body ingestion, but it was thought that hydrogen did not affect level of cholesterol system with which metabolic pathway is different from triglycerides and sugar.

However, it is checked that hydrogen controls a hydroxyl radical as antioxidants.

Evaluation of an energy generate ability on the cellular level accompanying hydrogen consumption

In order to verify hydrogen effects cellular level, The generate ability of energy in the erythrocyte of peripheral venous blood was measured.

Method

In order to verify hydrogen effects cellular level. As for this method this is described in the above patent application.

See figures 36-38.

Four 36 years old - 59 years

Cellular energy production index

Direction which is healthy now and is taking in hydrogen

Lactate

= The lactic acis / Pyruvate ratio in erythrocyte

Hydrogen is on a cellular level. Energy production and metabolisms are activated. Metabolic syndrome is also rivaled.

Example 13 – serious atopic disease

The patient was a female infant and 4 years old. When the patient together with her parents had visited the clinic, the remainder of the patient life was estimated with one month by the physician in charge of the hospital.

After that the patient had been administered with a dosage schedule of 4-6 capsules per day for 2 years with minus hydrogen product as set out above the patient was completely cured. The patient is now 6 years old and is very well.

The treatment condition and complete curing is reflected below and in figures 39 and 40.

The patient case of the Congenital Epidermolysis Bullosa (+Eczema)
4 years old (female infant)
The patient was a skin defect of terminal limb at birth. The patient was diagnosed with congenital epidermolysis bullosa by DNA examination test.
It was very strong with the itching sensation and then the symptom was worsened with breaking scratching within reach of her hand, during sleep.
The patient was constant malnutrition and constant state of anemia by reason of a frequent bleeding, fluid exudation and infection.

Since May, 2006, especially it was significant deterioration condition at breast・right lower extremity. And also CRP was shown high 6.2-9.6 mg/dl.

Since the end of December, 2006, the patient had ingested with minus hydrogen capsule (4-6 capsules/day) after then the strong itching sensation was shown a trend of light. And also breaks a vicious circle that was reduced by scraping.

Table 11

	May, 2006		**April, 2007**
	06'05		**07'04**
Alb	2.1		2.9
Hb	7.4		10.7
IgE	13100		6100
CRP	9.62		4.66

The present invention has been described above with reference to specific embodiments. However, other embodiments than the above described are equally possible within the scope of the invention. Different method steps than those described above, performing the method by hardware or software, may be provided within the scope of the invention. The different features and steps of the invention may be combined in other combinations than those described.

Various embodiments of the present invention have been described above but a person skilled in the art realizes further minor alterations, which would fall into the scope of the present invention. The breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents. For example, any of the above-noted compositions and methods can be combined with other known methods. Other aspects, advantages and modifications within the scope of the invention will be apparent to those skilled in the art to which the invention pertains.

CLAIMS

1. A hydrogen emitting composition for pharmaceutical use comprising a magnesium compound.

2. A composition for pharmaceutical use according to claim 1 wherein the magnesium compound is a magnesium hydride or a magnesium metal.

3. A composition for pharmaceutical use according to claim 2 wherein the composition comprises a magnesium hydride and a minus hydrogen ion material, both preferably in powder form.

4. A composition for pharmaceutical use according to claim 2 wherein the composition comprises a magnesium metal and a minus hydrogen ion material, both preferably in powder form.

5. A composition for pharmaceutical use according to claim 2 wherein the composition comprises a magnesium hydride, a calcium hydride and a halogen chloride, preferably NaCl, all preferably in powder form.

6. A composition for pharmaceutical use according to claim 2 wherein the composition comprises a magnesium metal, preferably in powder form, magnetic ceramic balls and activated carbon, preferably in powder form.

7. A composition according to any one of the preceding claims which is in liquid form or in solid form.

8. A composition according to claim 7 wherein the solid form is a capsule, tablet or a powder for suspending or immersing.

9. A composition according to claim 8 wherein the tablet also comprises crystalline cellulose and sucrose fatty acid.

10. A composition according to claim 8 wherein the powder for immersing is contained in a stick.

11. A composition according to claim 7 wherein the liquid form is a filtered liquid or a suspension.

12. A composition according to any one of the preceding claims also comprising CoQ10 or an analogue thereof.

13. A composition according to claim 12 wherein said analogue is alpha-tocopherol quinone, tocotrienol quinone, tocotrienol hydroquinone or Idebenone.

14. A composition according to claim 12 also comprising a vitamin and/or an antioxidant besides CoQ10 or an analogue set out in claim 13.

15. A composition according to claim 12 also comprising 4-(p-quinolyl)-2-hydroxybutanamide, 2-(3-hydroxy-3-methylbutyl)-6-(het)aryl-p-quinone or 2-(3- hydroxy-3-methylbutyl)-3-(het)aryl-p-quinone or a derivative thereof of said compounds.

16. A method for manufacturing a magnesium hydride set out in claim 3 for use in a composition according to any one of the preceding claims comprising the following steps:

a) providing magnesium oxide,

b) performing a reduction calcination of said magnesium oxide at about 650 °C and during about 6 hours under a gas atmosphere being a mix of N_2 and H_2, with a ratio of 90%:10%, and

c) milling of the reduction calcination end product and

d) optionally storing said milled reduction calcination end product and also optionally, filling the product obtained in step c) in containers.

17. A magnesium hydride obtainable by the method according to claim 16.

18. A method for manufacturing a composition according to claim 3 or 4 comprising the following steps:

e) mixing magnesium hydride or magnesium metal with a minus hydrogen ion material, all in powder form, and

f) filling the mix obtained in step e) into containers or into capsules, or tableting said mix into tablets, and optionally

g) if mix filled into capsules or tableted into tablets, packing said capsules or tablets in a container,

wherein preferably the magnesium hydride in powder form is a magnesium hydride according to claim 17.

19. A method for manufacturing a composition according to claim 5 comprising the following steps:

h) mixing a magnesium hydride, a calcium hydride and a halogen chloride, preferably NaCl, all in powder form,

i) distributing the mix of step h) into a liquid, preferably water, whereby letting the suspension to rest, and optionally

j) filtering the suspension and

k) filling the filtered liquid into a container or into bottles,

wherein preferably the magnesium hydride in powder form is a magnesium hydride according to claim 17.

20. A liquid obtainable by the method according to claim 19.

21. A method for manufacturing a composition according to claim 5 comprising the following steps:

l) mixing, a magnesium metal, preferably in powder form, magnetic ceramic balls and activated carbon , preferably in powder form,

m) filling said mix of step l) into a perforated container, preferably in the form of a stick, allowing a liquid when said container, preferably a stick, is submerged into a liquid to penetrate into said perforated container and

n) closing the entrance for filling of said container.

22. A container obtainable by the method according to claim 21.

23. Method for producing a hydrogen plasma water involving the following steps:

o) washing one or more compositions according to claim 5, preferably in the form of sticks, in a weak acidic liquid, preferably vinegar, and

p) inserting one of more of said washed compositions according to claim 5 in water and letting the water rest,

q) withdrawing said washed compositions from the water, and optionally
r) filling the water into a container or into bottles.

24. Water obtainable by the method according to claim 23.

25. Use of a composition according to claim 5 for producing a hydrogen plasma water.

26. Method for producing a minus hydrogen ion material as set out in claim 3 involving the following steps:
s) mixing a liquid, coral calcium powder and wheat, and preferably also silica, and forming into a dumpling like shape,
t) drying,
u) performing an oxidation calcination on the product of step t) at 720 °C and during about 8 hours,
v) performing a reduction calcination on the product of step u) at 650 °C and during about 6 hours under a gas atmosphere being a mix of N_2 and H_2, with ratio 90%:10%, and
w) milling the product of step v) and optionally,
x) filling the milled product obtained in step w) into containers or into capsules, or tableting said milled product into tablets, and also optionally if the milled product obtained in step w) filled into capsules or tableted into tablets, packing said capsules or tablets in a container.

27. A minus hydrogen ion material obtainable by the method according to claim 26.

28. Method for producing (a) magnetic ceramic ball(s) as set out in claim 6 involving the following steps:
y) mixing a clay, an iron oxide, coral calcium powder and a zeolite, and preferably also a liquid,
z) drying and forming the mix of step y) into (an) essentially spherical portion(s),
aa) performing an oxidation calcination on the product of step z) at 720 °C and during about 8 hours,
bb) performing a reduction calcination on the product of step aa) at 650 °C and during about 6 hours under a gas atmosphere being a mix of N_2 and H_2, with ratio 90%:10%, and
cc) performing a magnetizing process on the product of step bb) and optionally,
dd) filling the product obtained in step cc) into a container.

29. A magnetic ceramic ball obtainable by the method according to claim 28.

30. A method for treatment of an animal or human body whereby the composition according to any one of claims 1 - 15 is used.

31. A method according to claim 30 wherein the therapy is against cancer, wherein said cancer preferably is terminal cancer.

32. A method according to claim 31 wherein the therapy is against one or more tumors appearing on the surface of an animal or human body and/or inside of an animal or human body.

33. A method according to claim 32 wherein the tumor(s) appearing on the surface of an animal or human body is a melanoma or non-melanoma cancer.

34. A method according to claim 32 wherein the tumor(s) inside of an animal or human body, is one or more of a retina blastoma cancer, pancreatic cancer, liver cancer, prostate cancer, ovarian cancer, gastric cancer, bile duct cancer, bladder cancer, colon cancer, epithelial cancer, breast cancer, oral cancer, nasal cancer, osteosarcomas, head cancer, neck cancer, brain cancer, peritoneal cancer, esophageal cancer, kidney cancer, lung cancer, cancer in the nerves, barretts esophagus, basal cell carcinoma, cervical cancer, esophagus cancer, gastrointestinal cancer, gynecology diseases, testicular cancer, rectal cancer and hpv warts.

35. A method according to claim 30 wherein the therapy is against pain.

36. A method according to claim 30 wherein the therapy is against a geriatric disorder.

37. A method according to claim 36 wherein the geriatric disorder is one or more of hypertension, cholesterol, hyperlipemia and diabetes, preferably hyperlipemia.

38. A method according to claim 30 wherein the therapy is promoting hormonal secretion.

39. A method according to claim 30 wherein the dosage regime is 1 capsule a day.

40. A method according to claim 39 wherein the dosage regime is two capsules before exercise.

41. A method according to claim 30 wherein the indication is hair loss.

42. A method according to claim 30 wherein the indication is stress symptoms.

43. A method according to claim 30 wherein the indication is loss of sexual capacity.

44. A method according to claim 30 wherein the indication is an inflammation.

45. A method according to claim 30 wherein the indication is a mitochondrial disease.

46. A method according to claim 45 wherein the mitochondrial disease is an orphan mitochondrial disease, preferably Duchenne muscular dystrophy or progressive aging syndrome.

47. A method according to claim 45 wherein the mitochondrial disease is associated with a point mutation of the DNA, preferably mitochondrial myopathy, encephalopathy, lactic acidosis and stroke-like episodes (MELAS syndrome), Kearns-Sayre Syndrome (KSS), primary progressive multiple sclerosis , Leber's hereditary optic neuropathy, dominant optic atrophy or Friedrich´s ataxia.

48. A method according to claim 45 wherein the mitochondrial disease is Huntington´s disease, adult neurodegenerative disease, amyotrophic lateral sclerosis (ALS), Parkinson's disease or pervasive developmental disorder such as autism.

49. A method according to claim 45 wherein the mitochondrial disease is blindness.

50. A method according to claim 30 wherein the therapy is against osteoporosis, arthritis or chronic anti-inflammatory diseases.

51. A method according to claim 30 wherein the therapy is against a skin disease selected from the group comprising serious atopic dermatitis, Congenital Epidermolysis Bullosa, psoriasis, eczema or inflammatory bowel disease and combinations thereof.

52. A method according to claim 39 wherein the dosage regime is four to six capsules a day in case of a skin disease as set out in claim 51.

53. A method according to claim 30 wherein the therapy is against obesity.

54. Composition comprising magnesium for use in treating an indication or in a therapy as set out in claims 30-53.

55. Composition according to claim 54 comprising a magnesium hydride or a magnesium metal, for use in treating an indication or in a therapy as set out in claims 30-53.

56. Composition comprising a magnesium hydride according to claim 17 for use in treating an indication or in a therapy as set out in claims 30-53.

57. A liquid according to claim 20 for use in treating an indication or in a therapy as set out in claims 30-53.

58. A container according to claim 22 for use in treating an indication or in a therapy as set out in claims 30-53.

59. Water according to claim 24 for use in treating an indication or in a therapy as set out in claims 30-53.

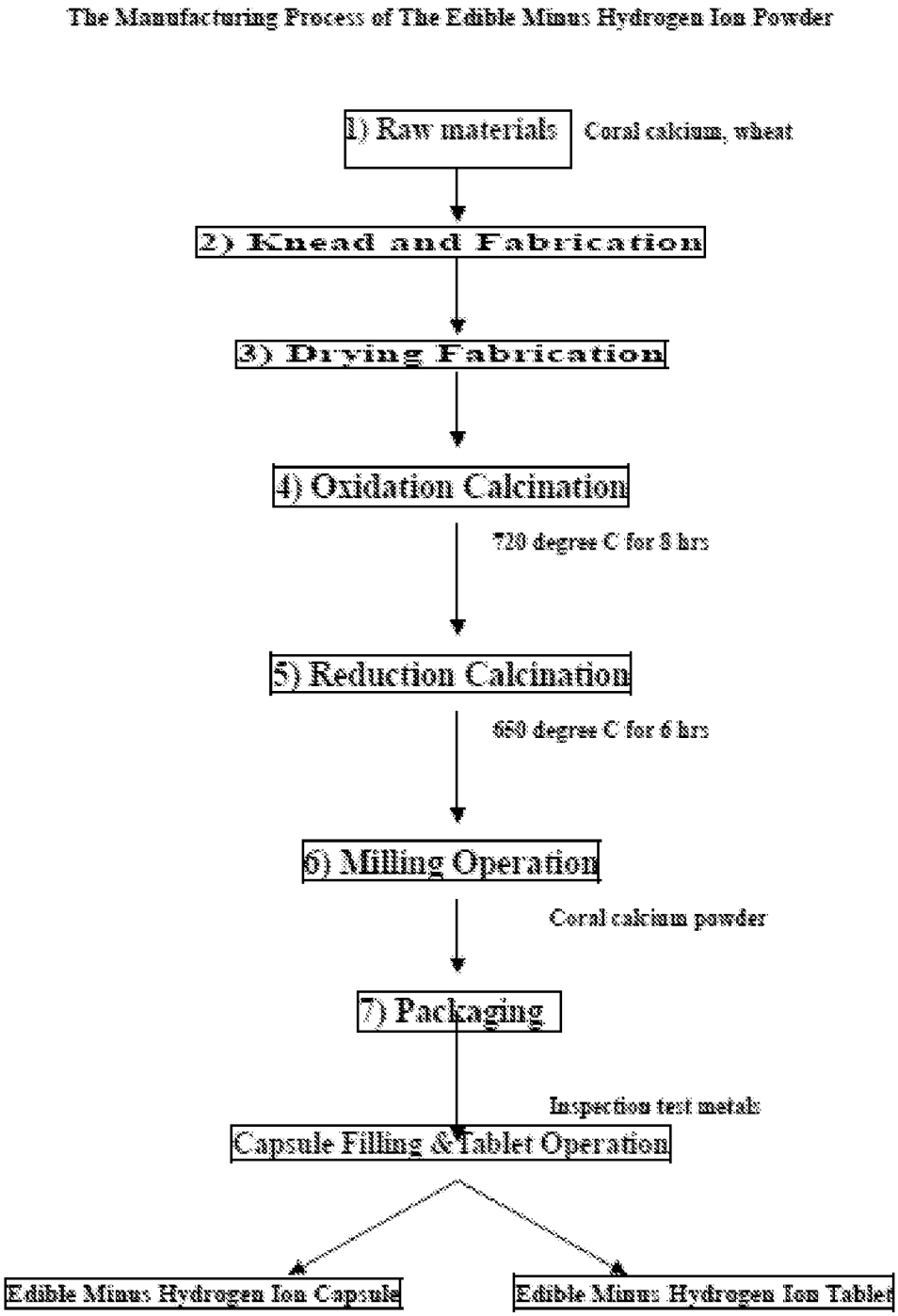
60. A magnetic ceramic ball according to claim 29 for use in treating an indication or in a therapy as set out in claims 30-53.

61. A kit comprising a weak acidic liquid and a container, preferably in the form of a stick, according to claim 22.

62. A method in accordance with the description and the drawings.

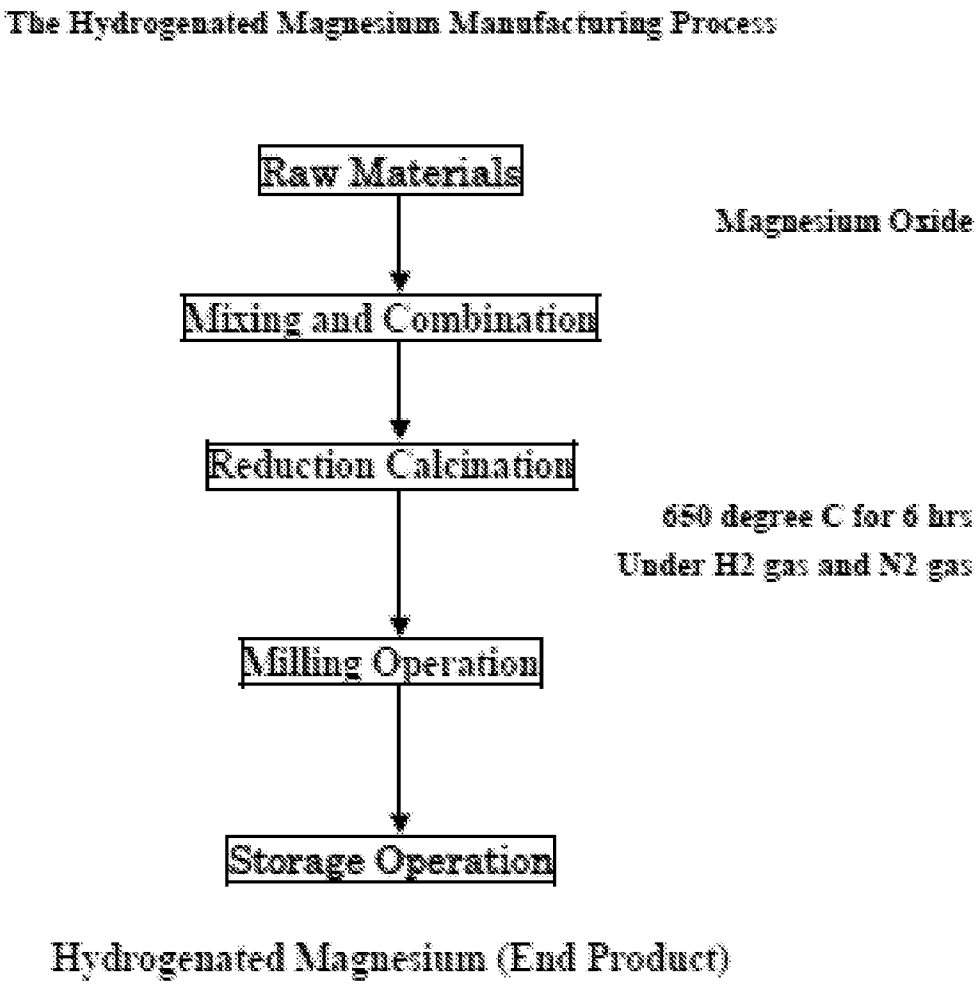
Figure 1

5


The Manufacturing Process of The Edible Minus Hydrogen Ion Powder
1) Raw materials
Coral calcium, wheat
2) Knead and Fabrication
3) Drying Fabrication
4) Oxidation Calcination
720 degree C for 8 hrs
5) Reduction Calcination
660 degree C for 6 hrs
6) Milling Operation
Coral calcium powder
7) Packaging
Inspection test metals
Capsule Filling & Tablet Operation
Edible Minus Hydrogen Ion Capsule
Edible Minus Hydrogen Ion Tablet

2/28

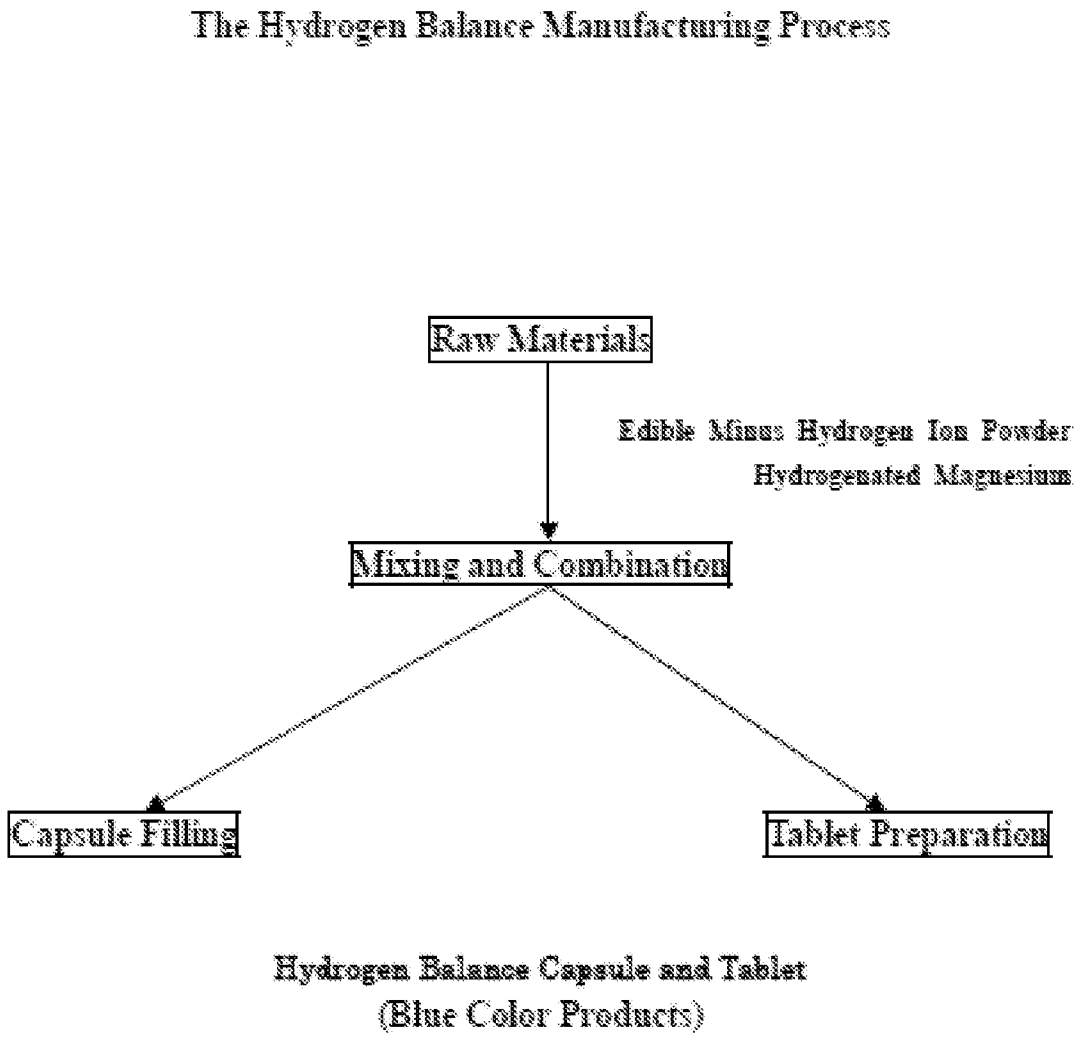
Figure 2



5

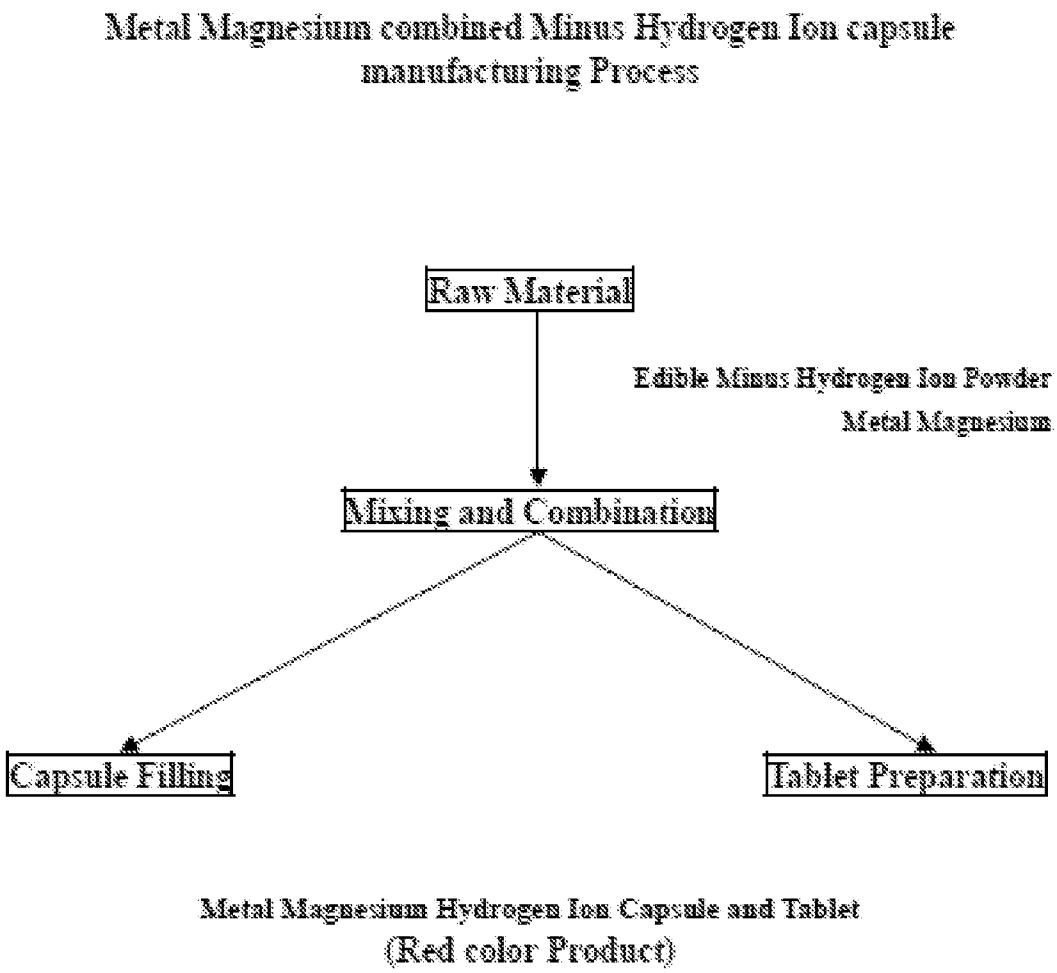
Figure 3

5



Hydrogen Balance Capsule and Tablet
(Blue Color Products)

Figure 4


Metal Magnesium combined Minus Hydrogen Ion capsule manufacturing Process
Raw Material
Edible Minus Hydrogen Ion Powder
Metal Magnesium
Mixing and Combination
Capsule Filling
Tablet Preparation
Metal Magnesium Hydrogen Ion Capsule and Tablet
(Red color Product)

5

Figure 5

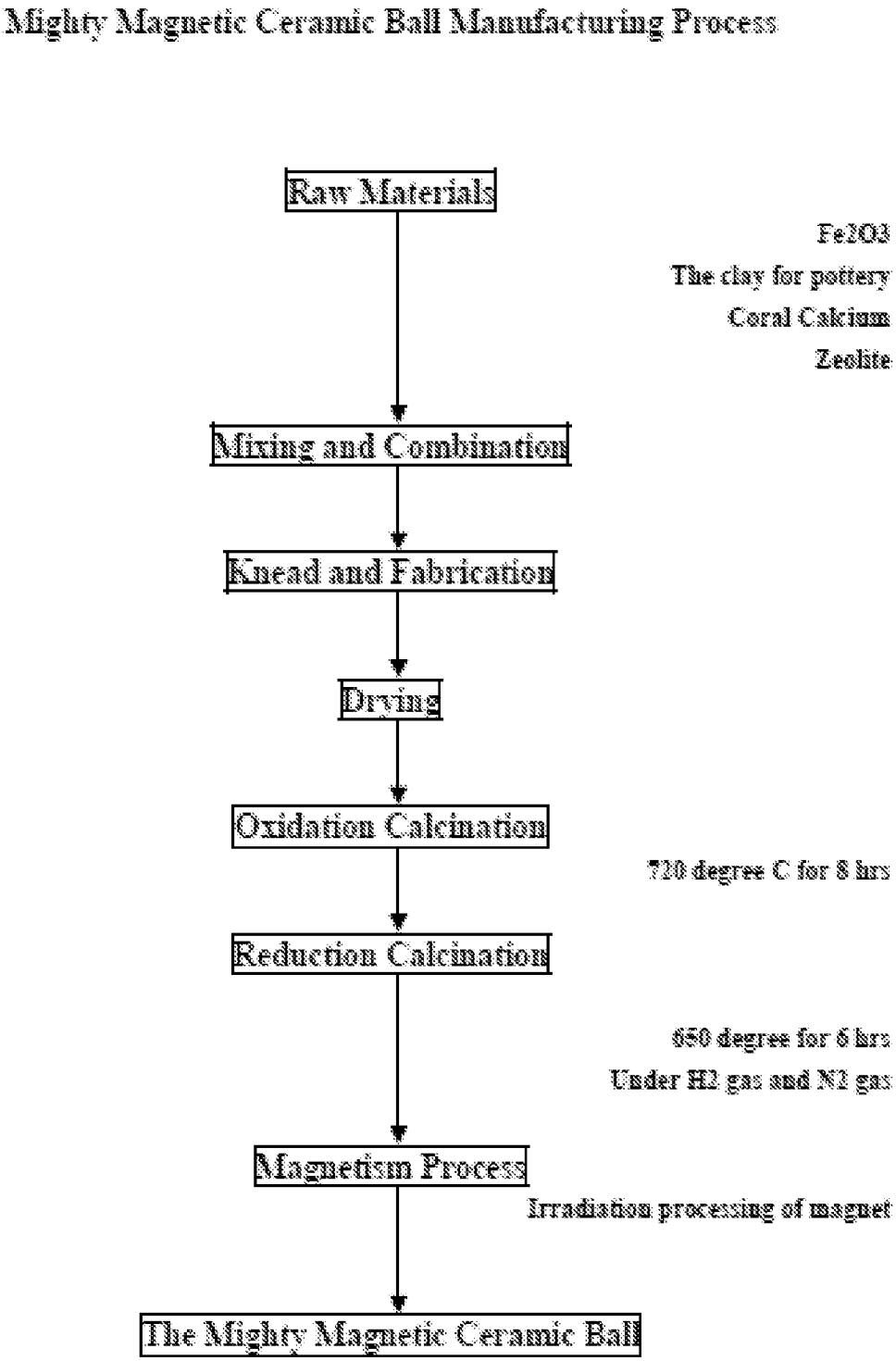
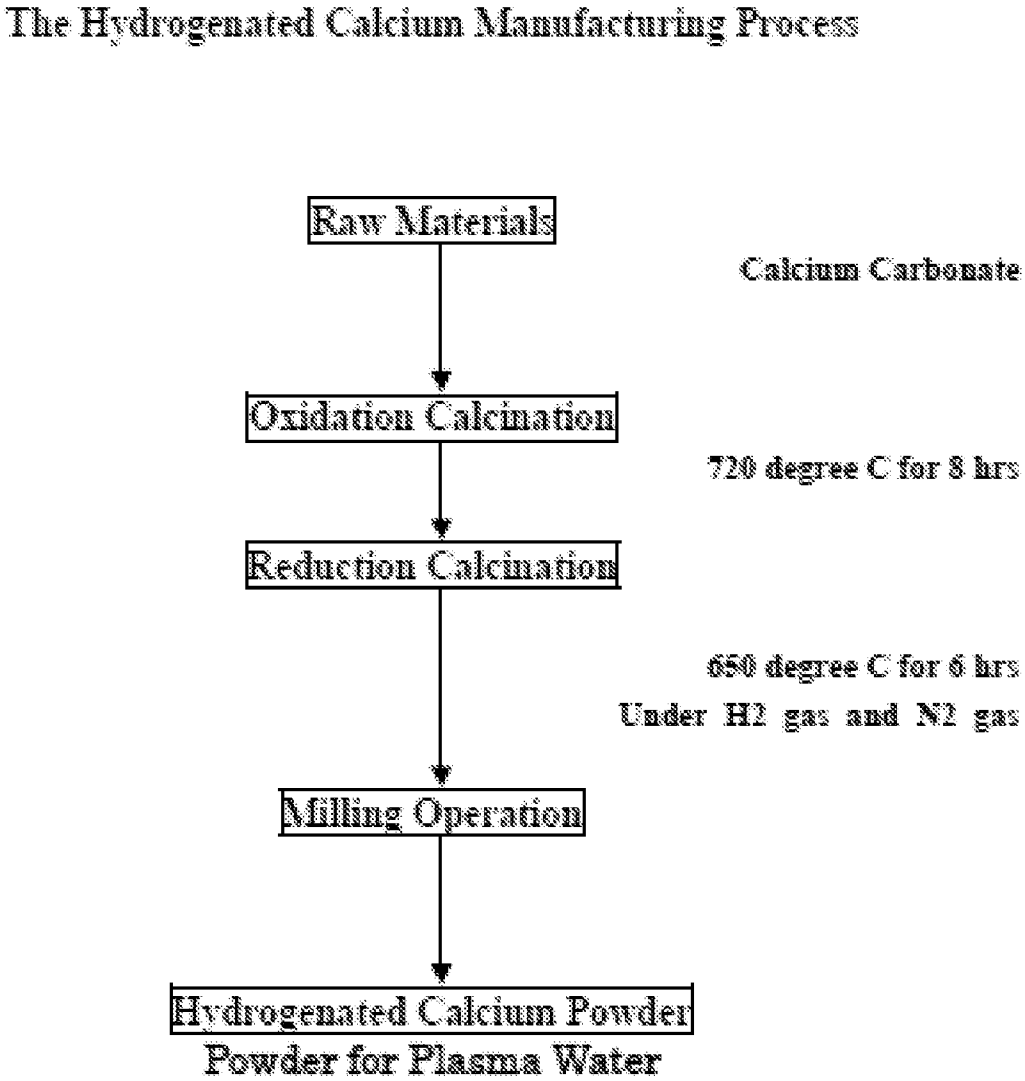

Mighty Magnetic Ceramic Ball Manufacturing Process
Raw Materials
Fe3O3
The clay for pottery
Coral Calcium
Zeolite
Mixing and Combination
Knead and Fabrication
Drying
Oxidation Calcination
720 degree C for 8 hrs
Reduction Calcination
650 degree for 6 hrs
Under H2 gas and N2 gas
Magnetism Process
Irradiation processing of magnet
The Mighty Magnetic Ceramic Ball

Figure 6


The Hydrogenated Calcium Manufacturing Process
Raw Materials
Calcium Carbonate
Oxidation Calcination
720 degree C for 8 hrs
Reduction Calcination
650 degree C for 6 hrs
Under H2 gas and N2 gas
Milling Operation
Hydrogenated Calcium Powder
Powder for Plasma Water

5

Figure 7

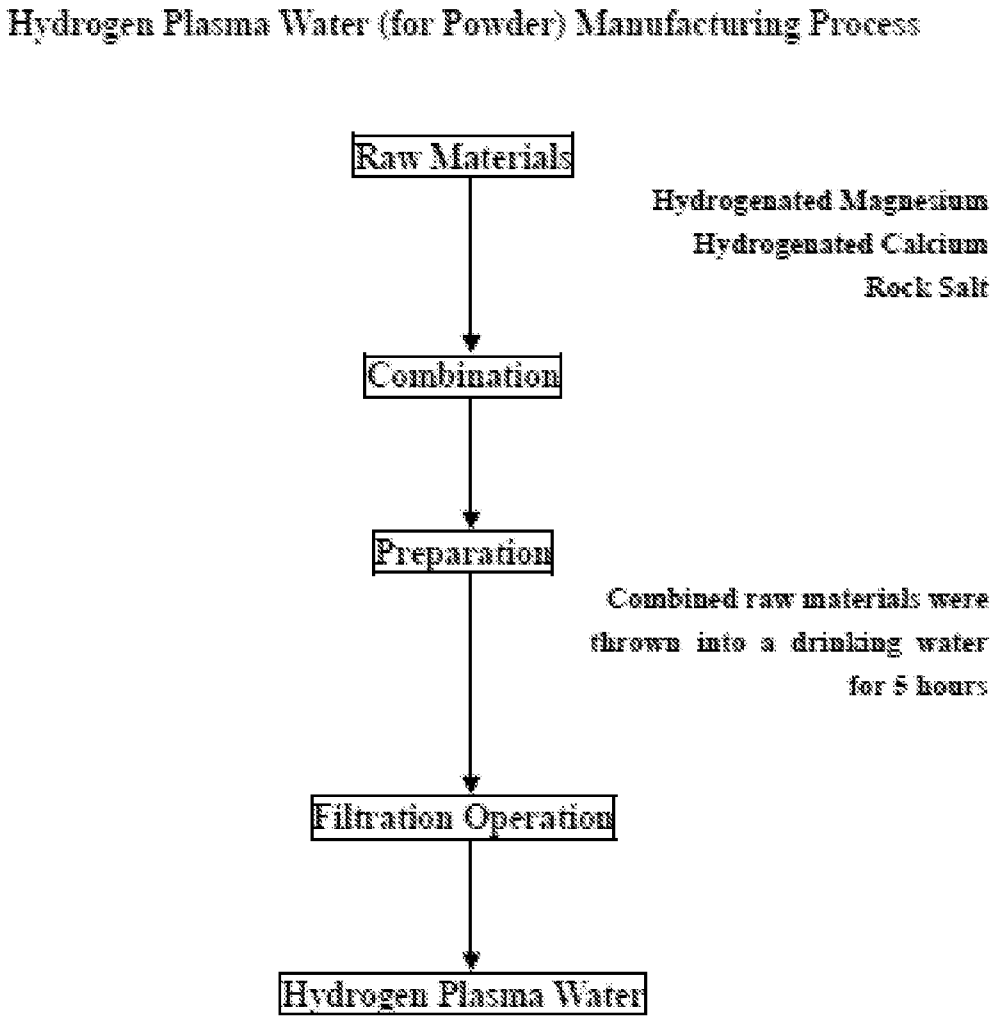
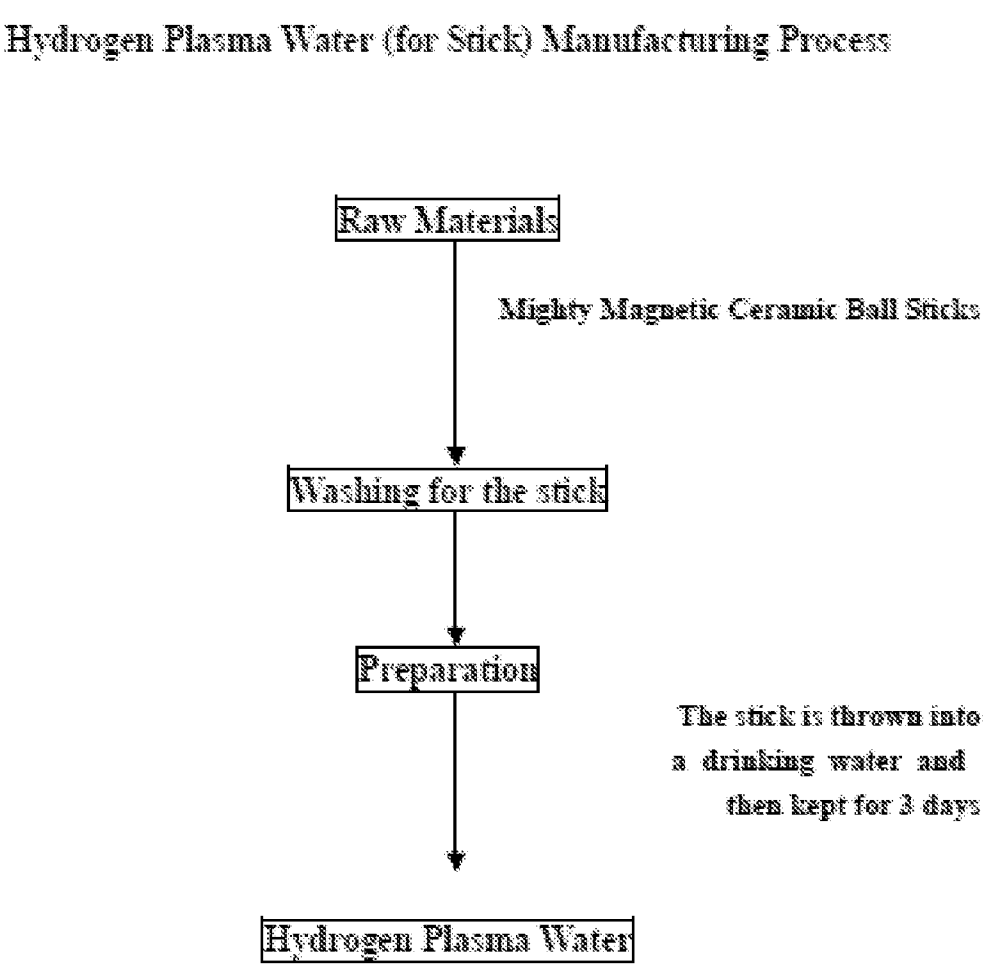
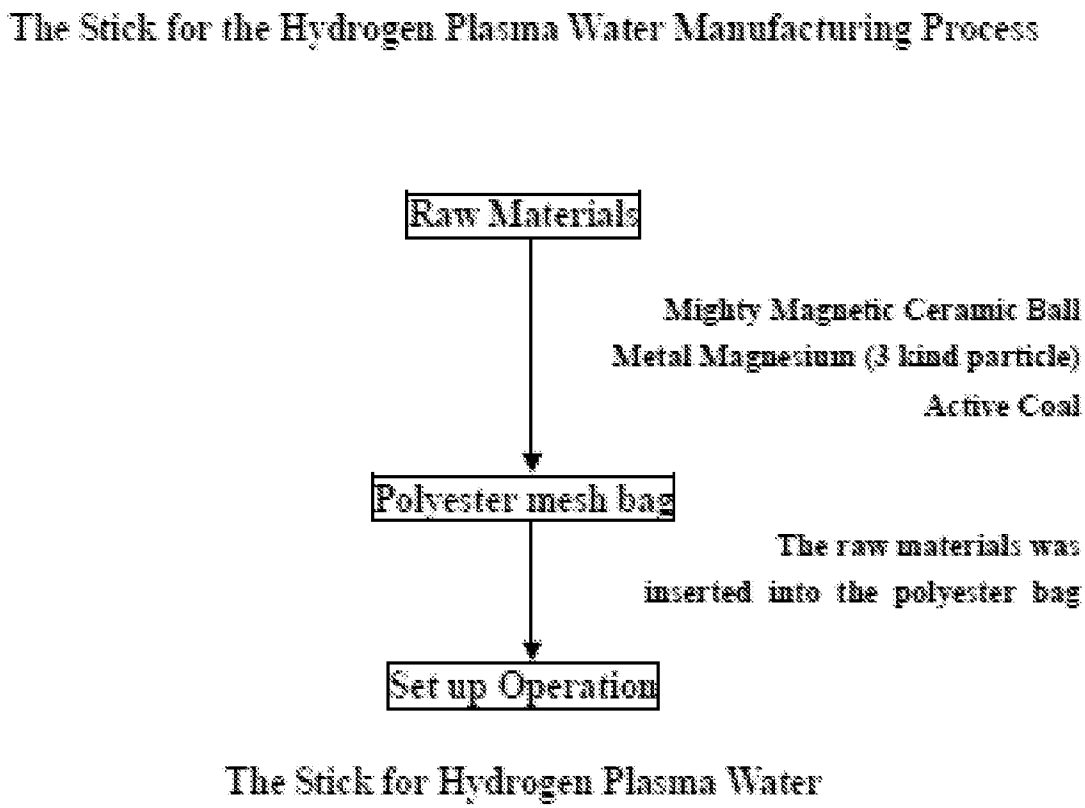

Hydrogen Plasma Water (for Powder) Manufacturing Process
Raw Materials
Hydrogenated Magnesium
Hydrogenated Calcium
Rock Salt
Combination
Preparation
Combined raw materials were thrown into a drinking water for 5 hours
Filtration Operation
Hydrogen Plasma Water

Figure 8


Hydrogen Plasma Water (for Stick) Manufacturing Process
Raw Materials
Mighty Magnetic Ceramic Ball Sticks
Washing for the stick
Preparation
The stick is thrown into a drinking water and then kept for 3 days
Hydrogen Plasma Water

5

Figure 9


The Stick for the Hydrogen Plasma Water Manufacturing Process
Raw Materials
Mighty Magnetic Ceramic Ball
Metal Magnesium (3 kind particle)
Active Coal
Polyester mesh bag
The raw materials was
inserted into the polyester bag
Set up Operation
The Stick for Hydrogen Plasma Water

5

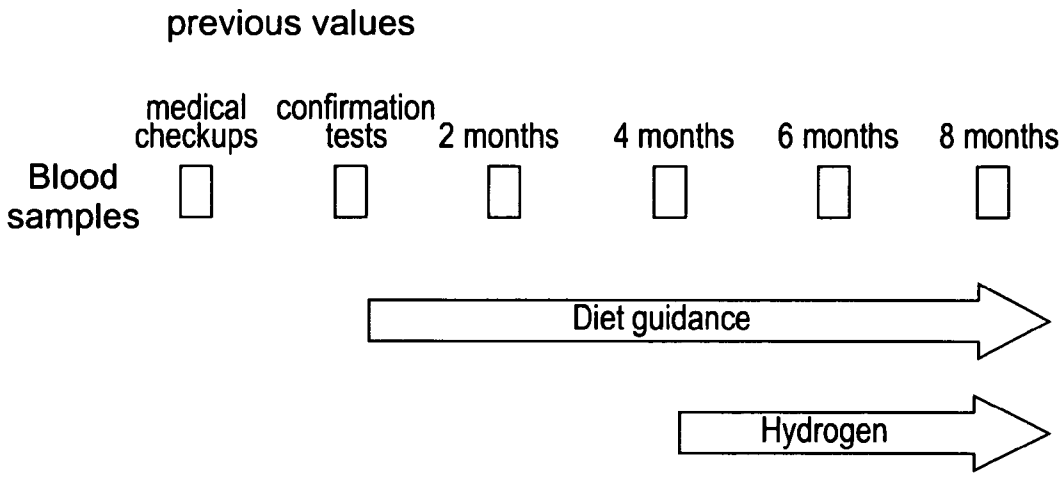


Figure 10

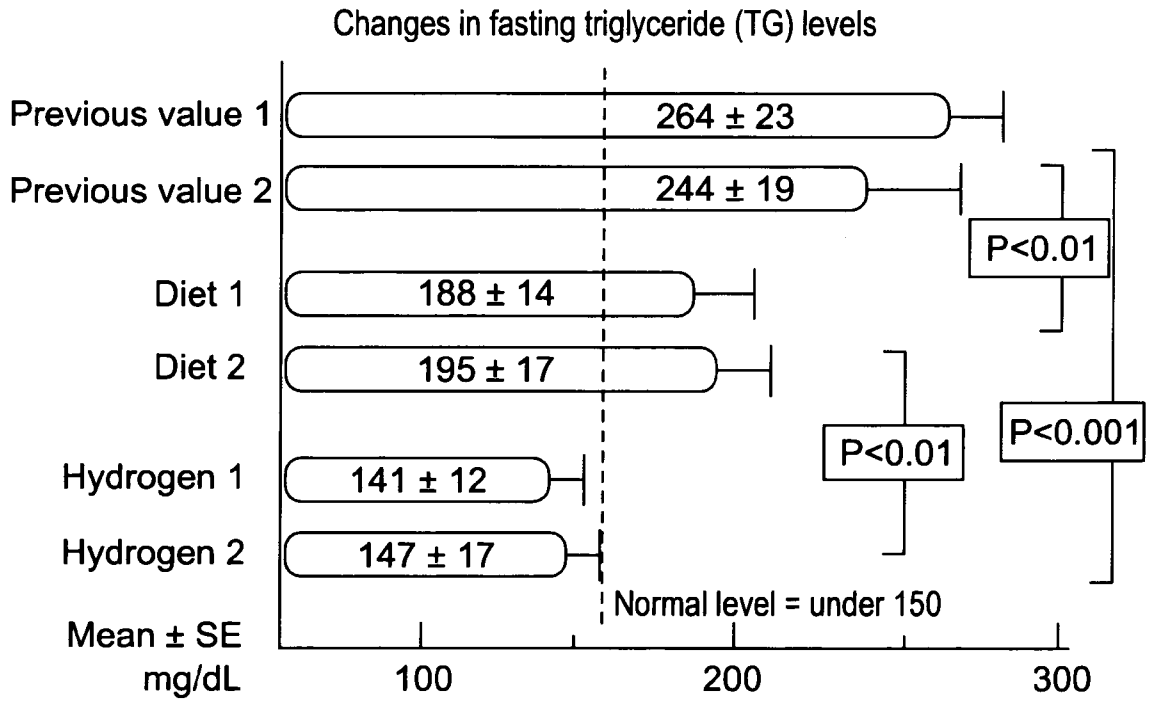


Figure 11

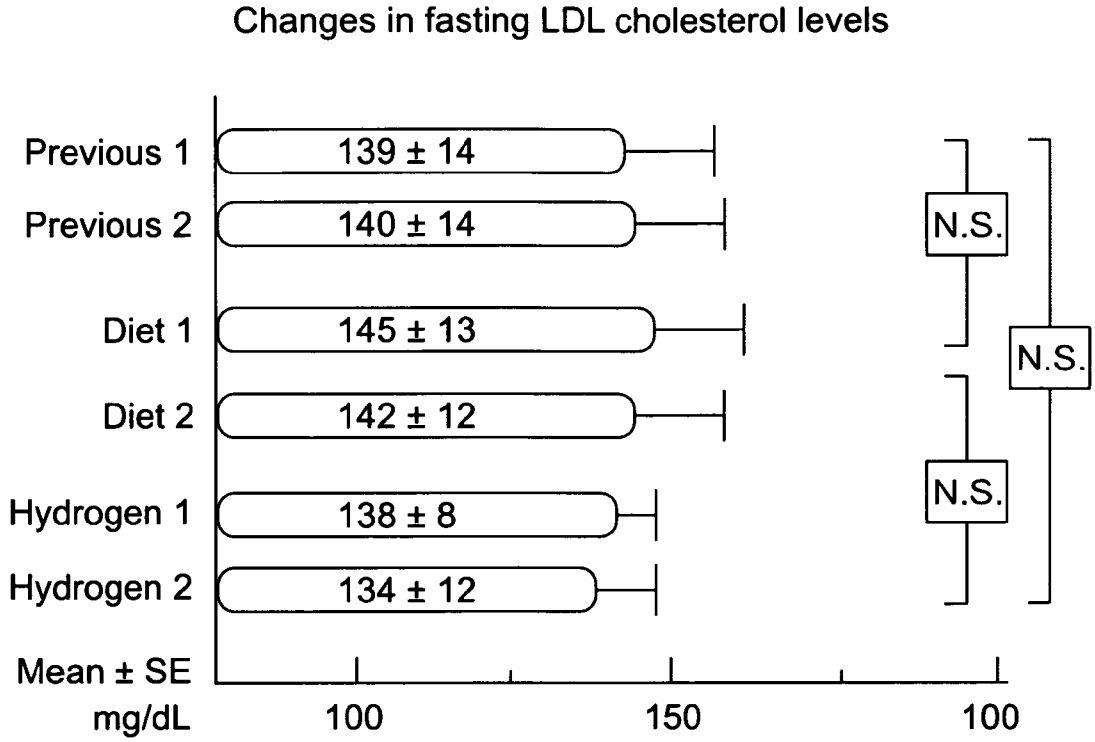


Figure 12

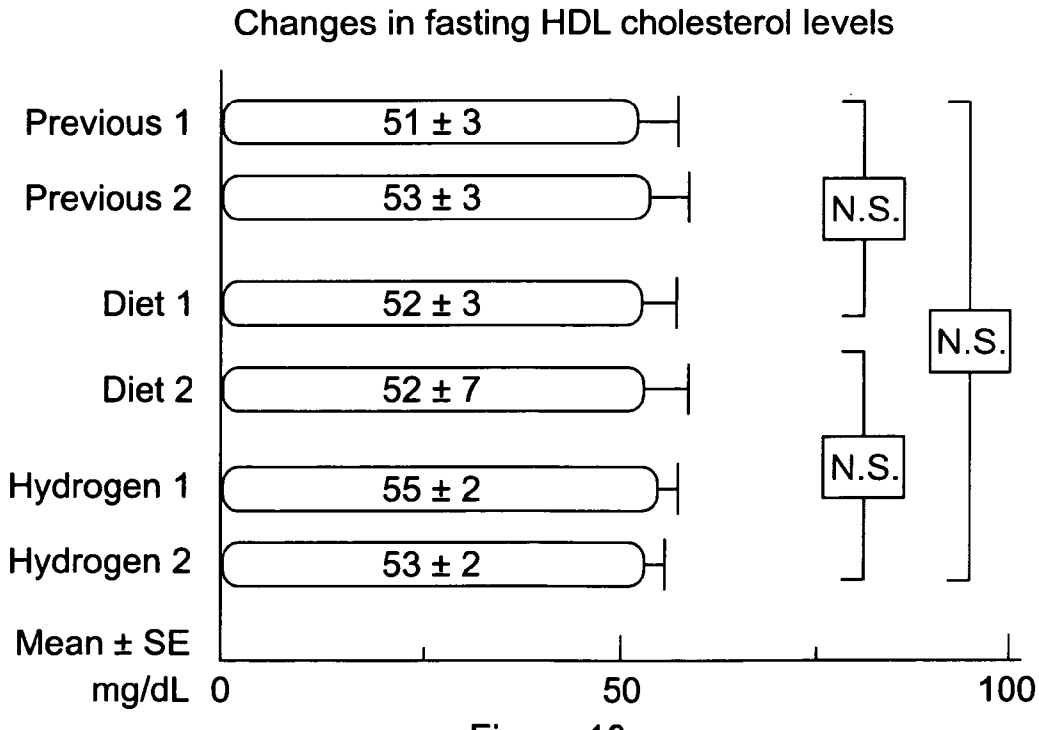


Figure 13

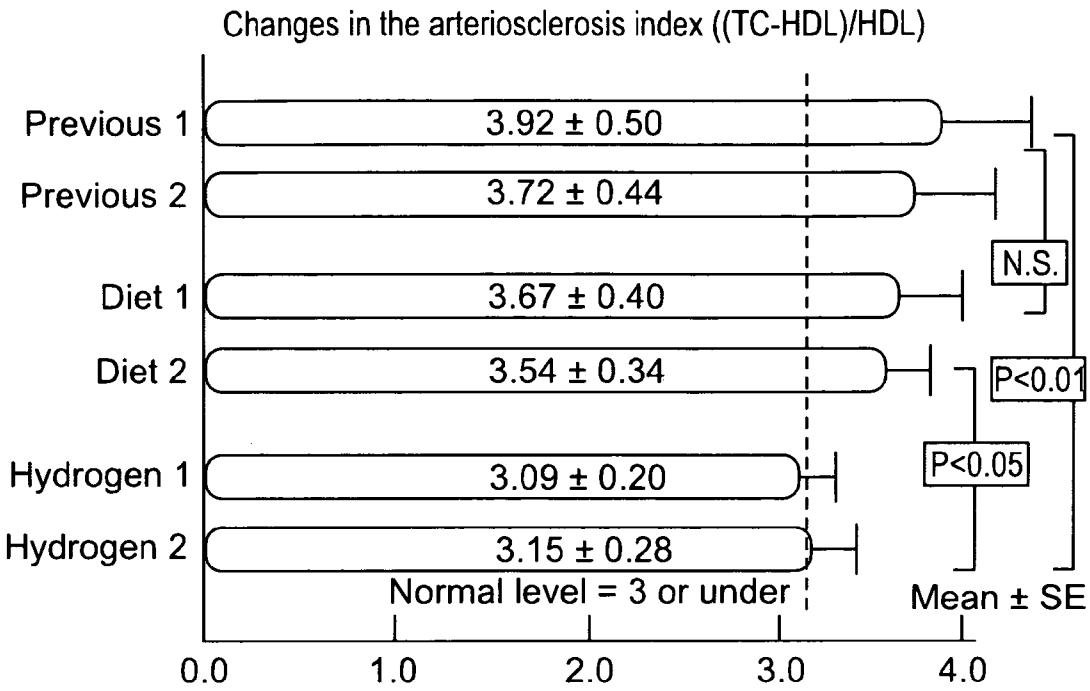


Figure 14

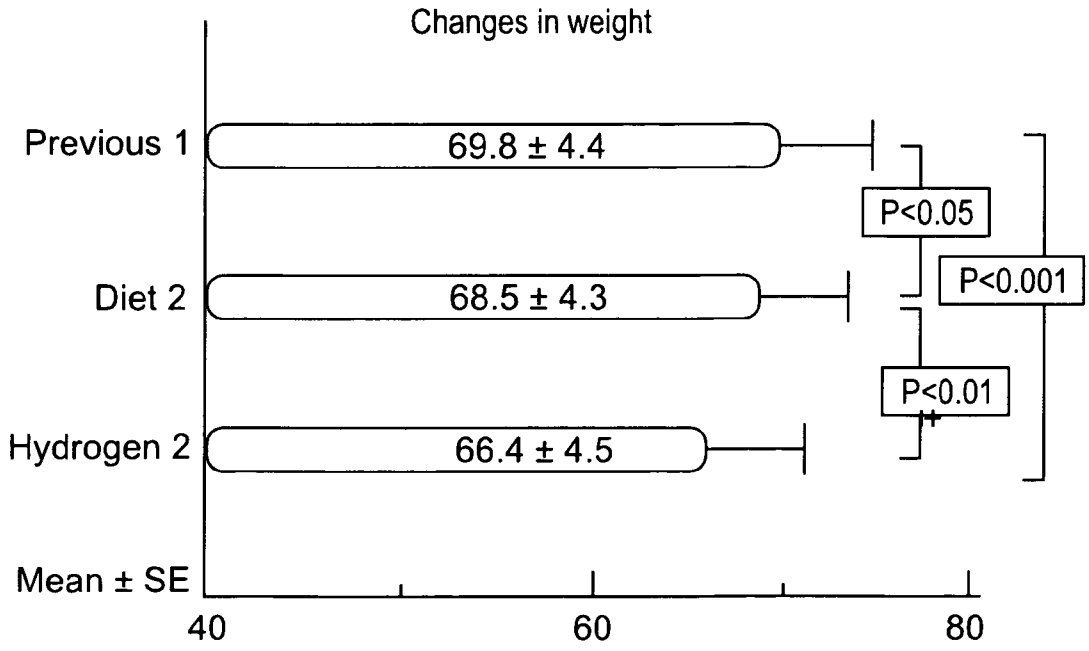


Figure 15

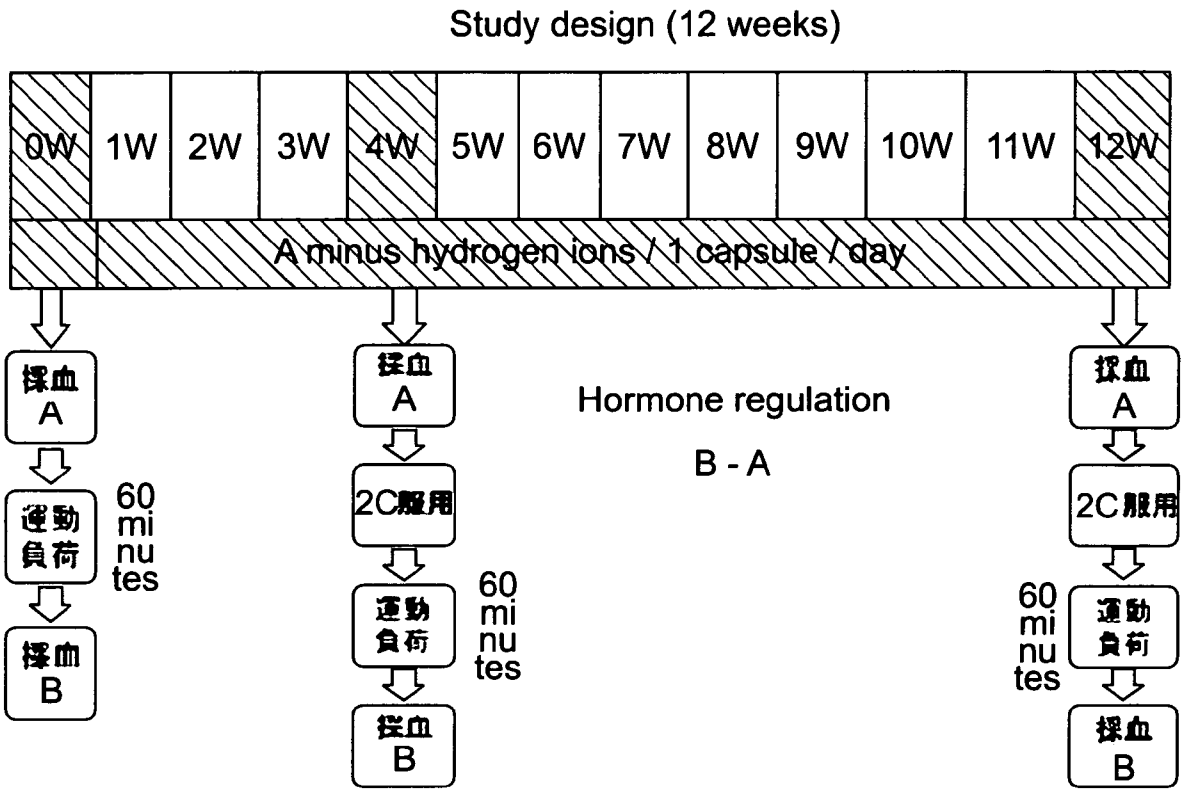

Study design (12 weeks)
0W
1W
2W
3W
4W
5W
6W
7W
8W
9W
10W
11W
12W
A minus hydrogen ions / 1 capsule / day
採血 A
運動負荷
60 minutes
採血 B
採血 A
2C服用
運動負荷
60 minutes
採血 B
Hormone regulation
B - A
採血 A
2C服用
60 minutes
運動負荷
採血 B

Figure 16

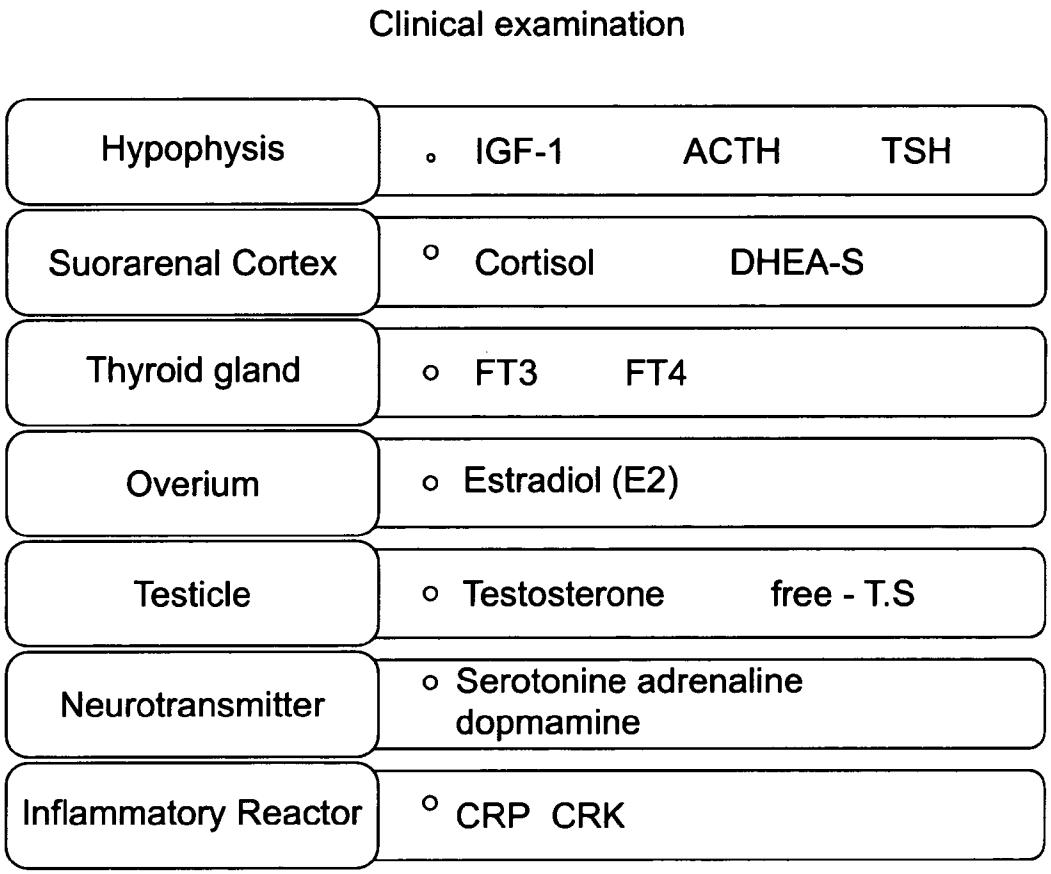

Clinical examination
Hypophysis
IGF-1 ACTH TSH
Suorarenal Cortex
Cortisol DHEA-S
Thyroid gland
FT3 FT4
Overium
Estradiol (E2)
Testicle
Testosterone free - T.S
Neurotransmitter
Serotonine adrenaline dopmamine
Inflammatory Reactor
CRP CRK

Figure 17

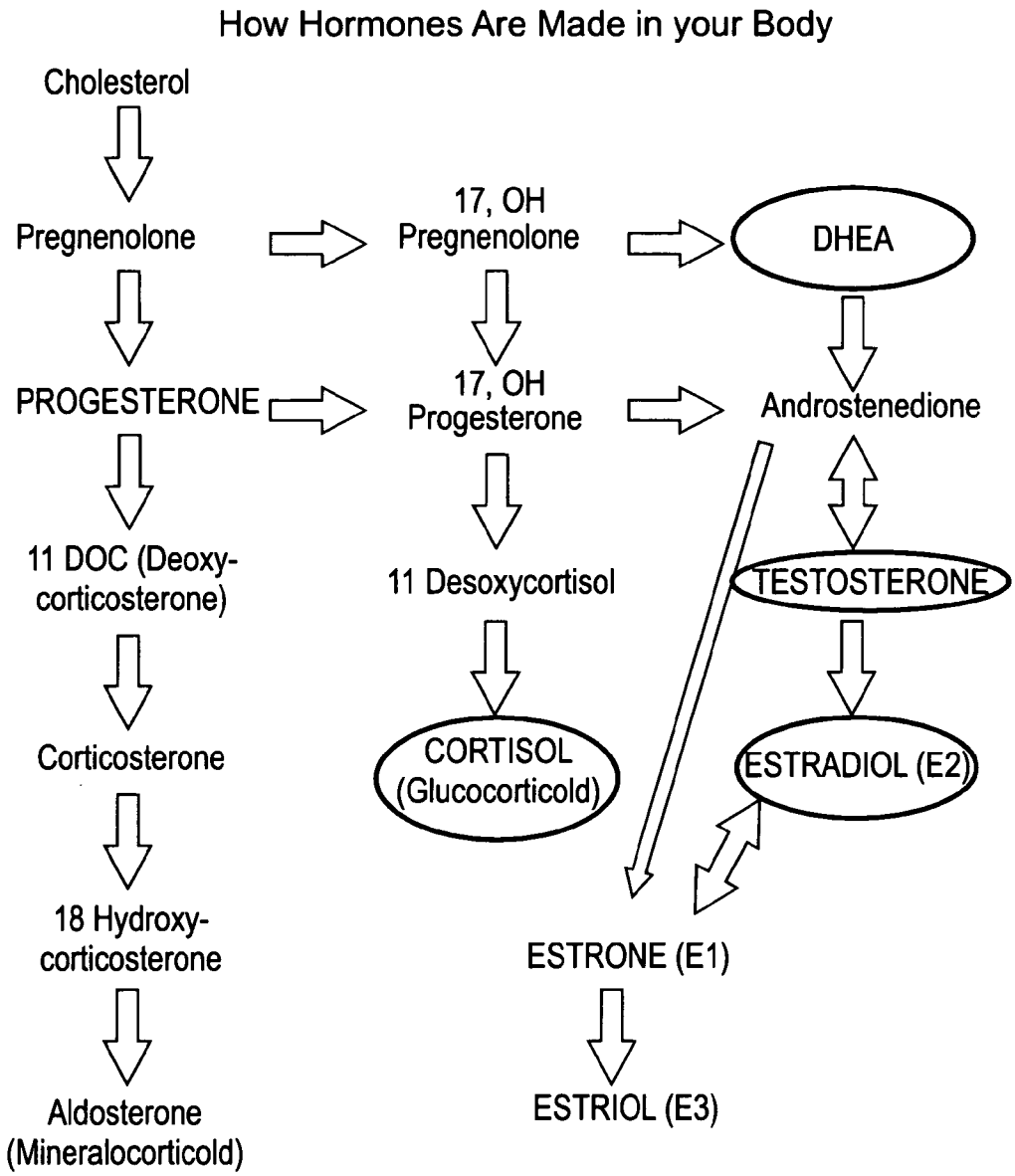

How Hormones Are Made in your Body
Cholesterol
Pregnenolone
PROGESTERONE
11 DOC (Deoxy-corticosterone)
Corticosterone
18 Hydroxy-corticosterone
Aldosterone (Mineralocorticold)
17, OH Pregnenolone
17, OH Progesterone
11 Desoxycortisol
CORTISOL (Glucocorticold)
DHEA
Androstenedione
TESTOSTERONE
ESTRADIOL (E2)
ESTRONE (E1)
ESTRIOL (E3)

Figure 18

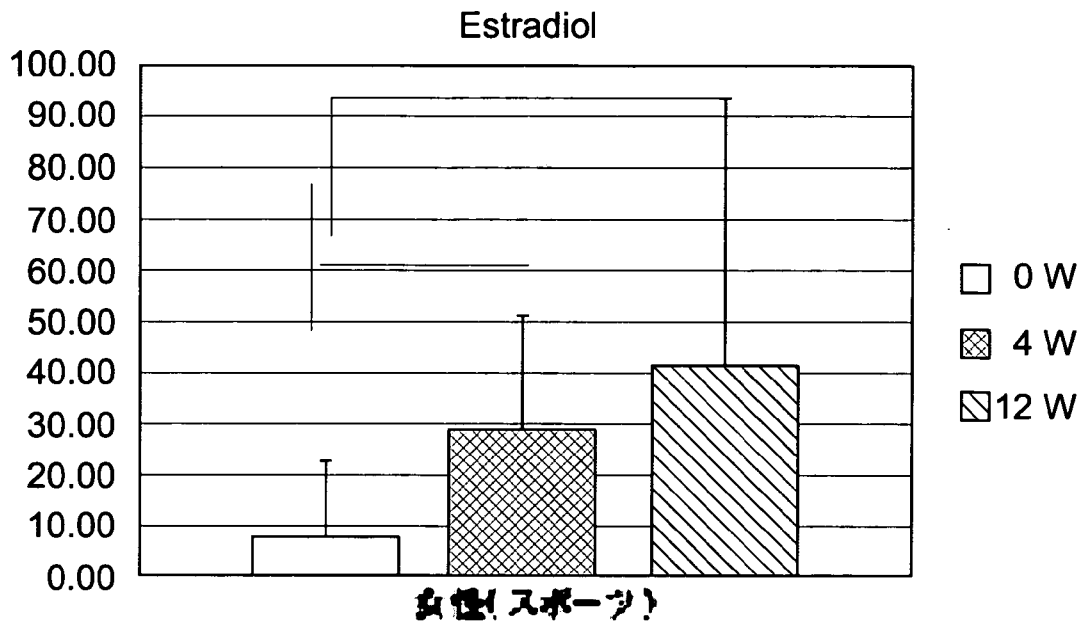


Figure 19

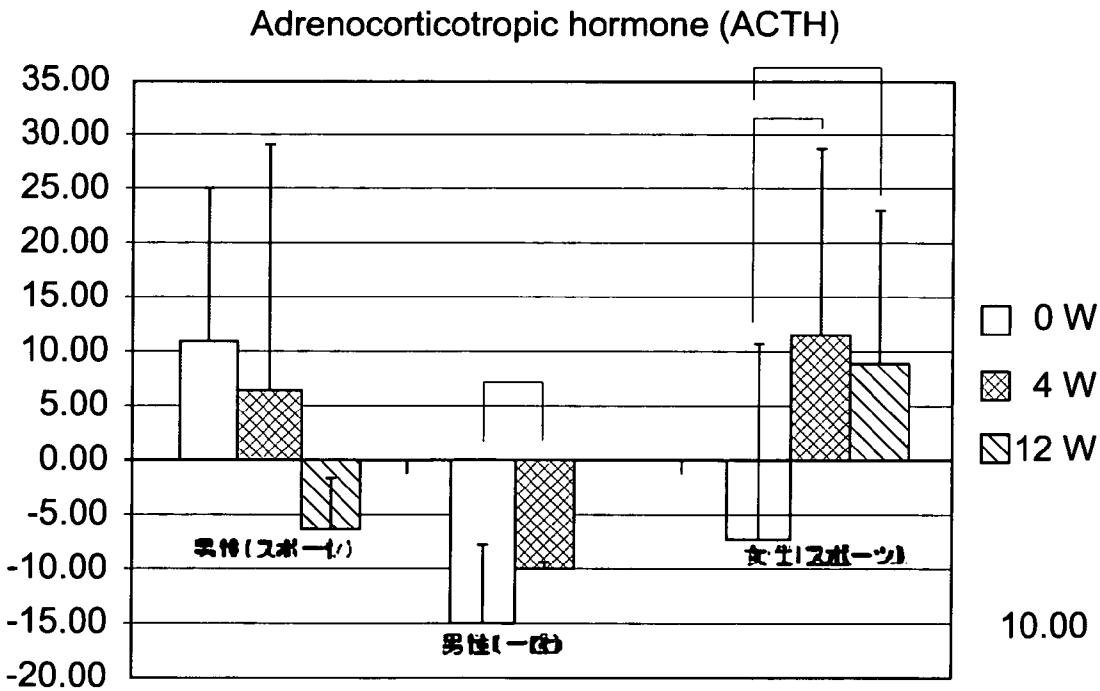


Figure 20

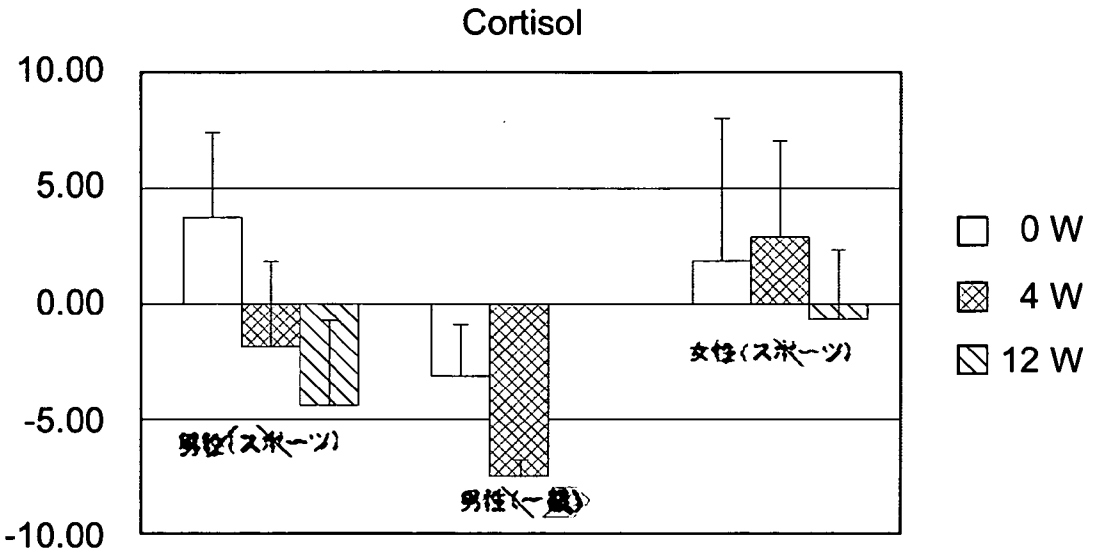


Figure 21

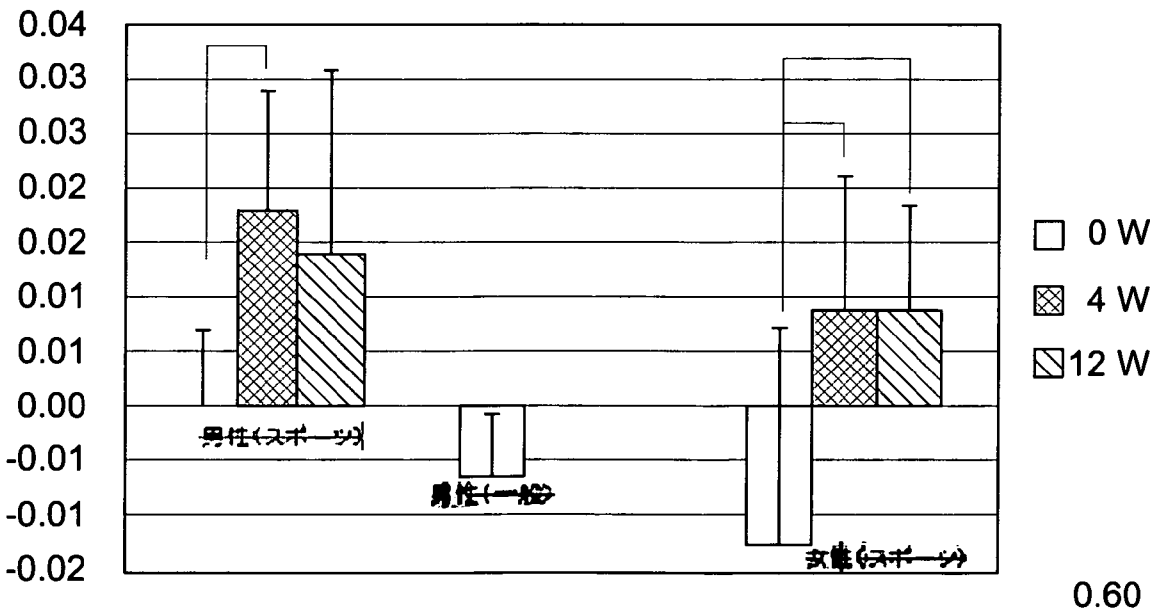


Figure 22

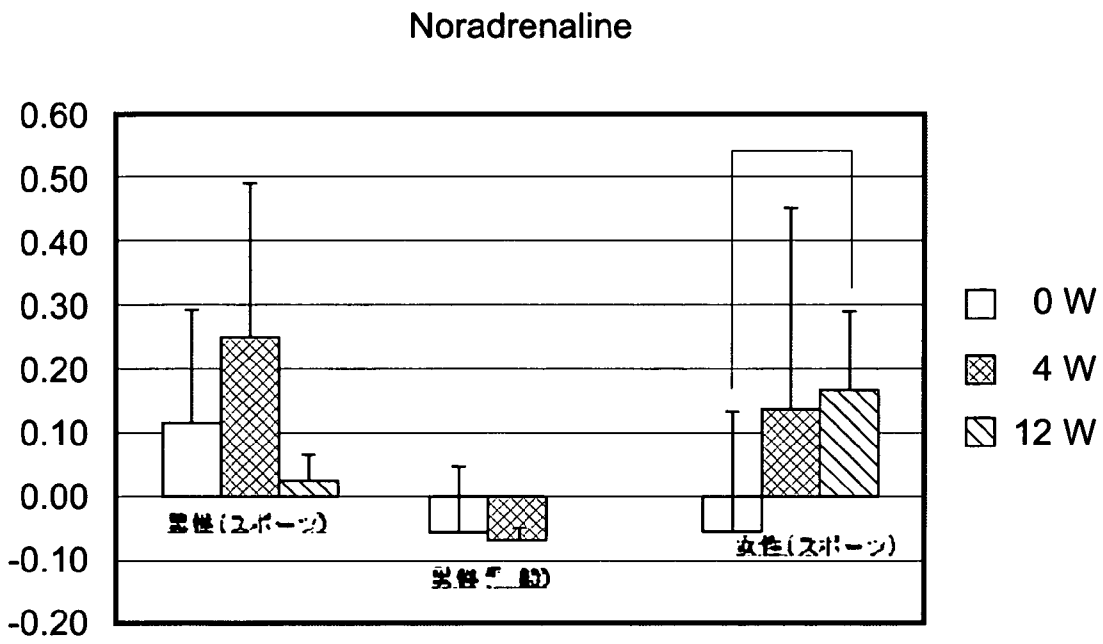


Figure 23

Figure 24

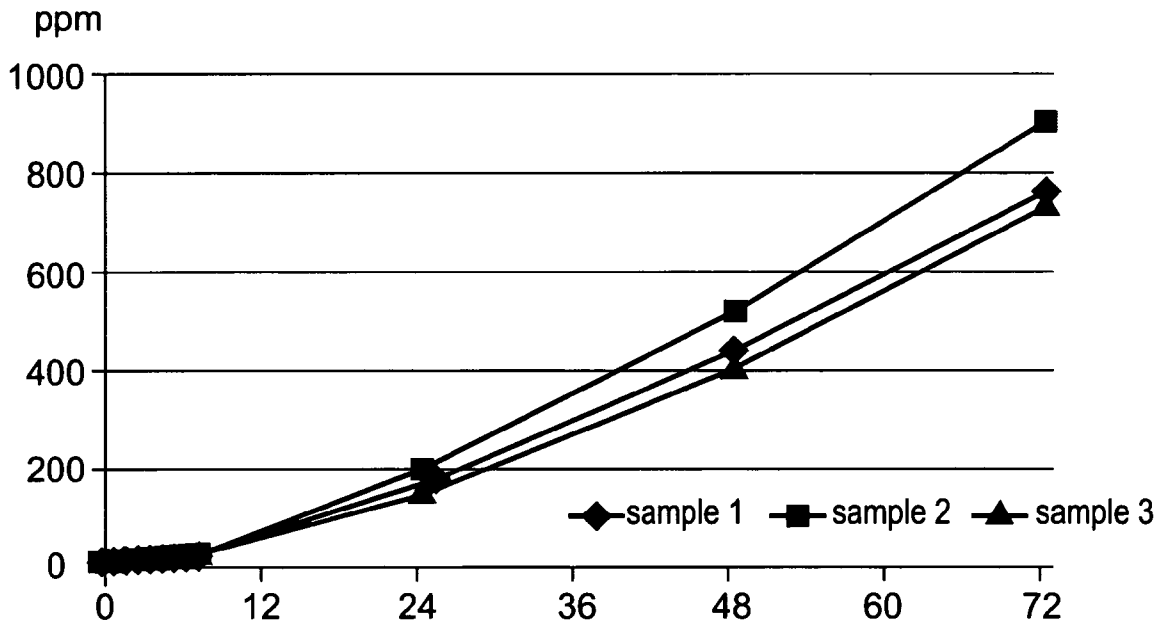


Figure 25

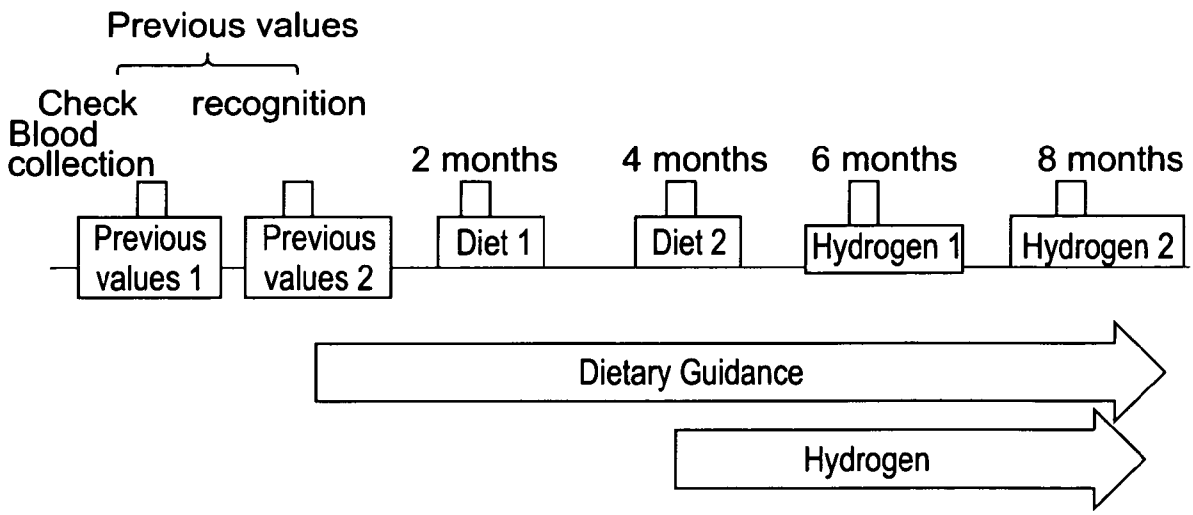


Figure 26

It is change of neutral fat (TG) at the time of hungry.

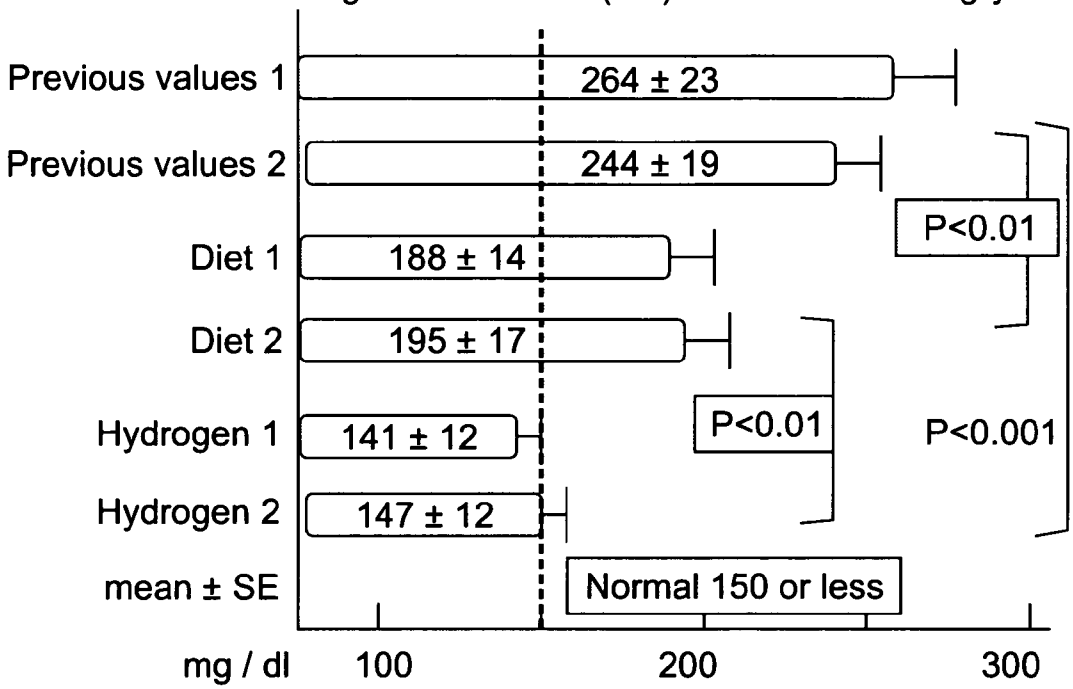


Figure 27

It is change of total cholesterol (TC) at the time of hungry.

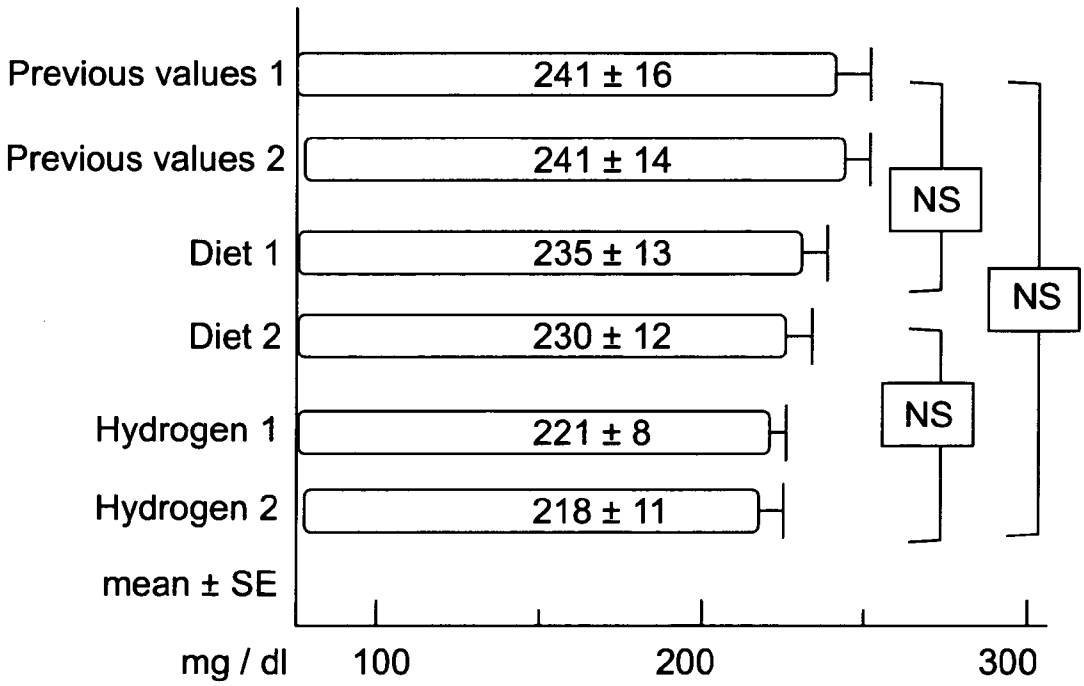


Figure 28

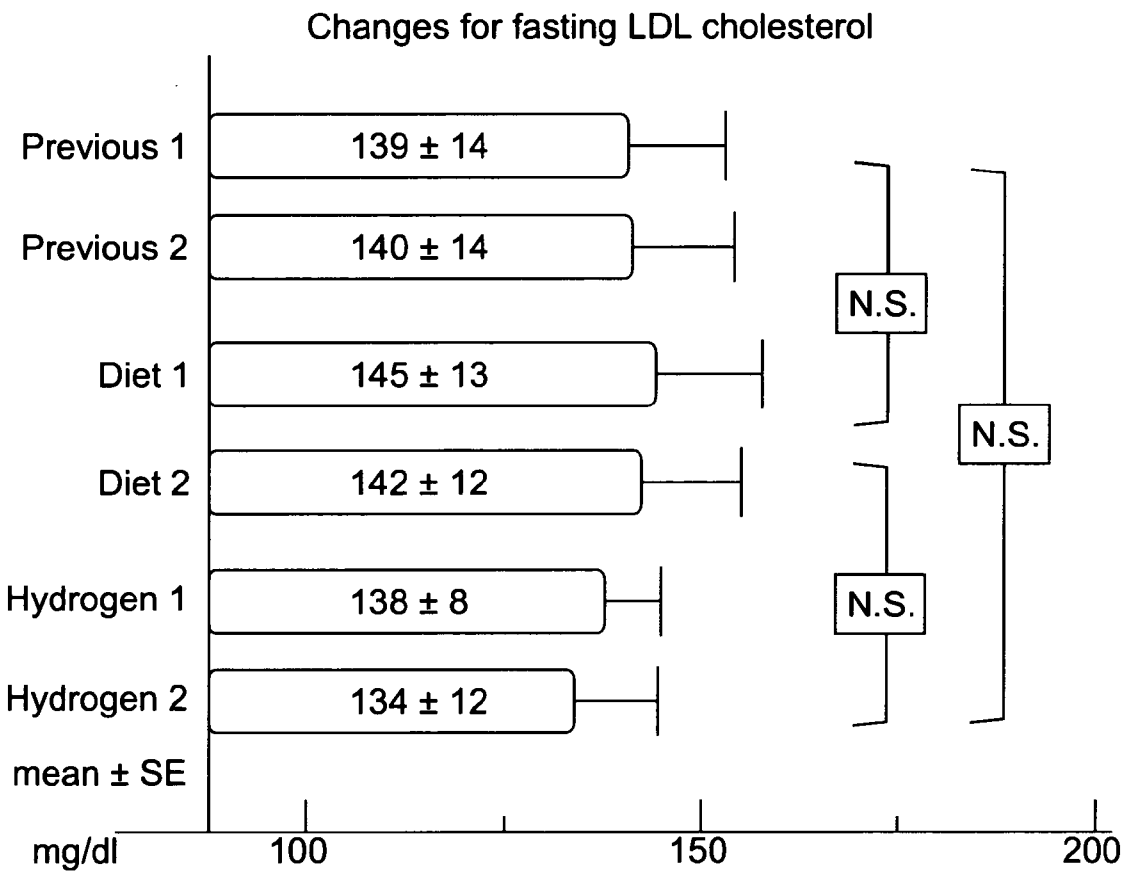

Changes for fasting LDL cholesterol
Previous 1
139 ± 14
Previous 2
140 ± 14
Diet 1
145 ± 13
Diet 2
142 ± 12
Hydrogen 1
138 ± 8
Hydrogen 2
134 ± 12
mean ± SE
mg/dl
100
150
200
N.S.
N.S.
N.S.

Figure 29

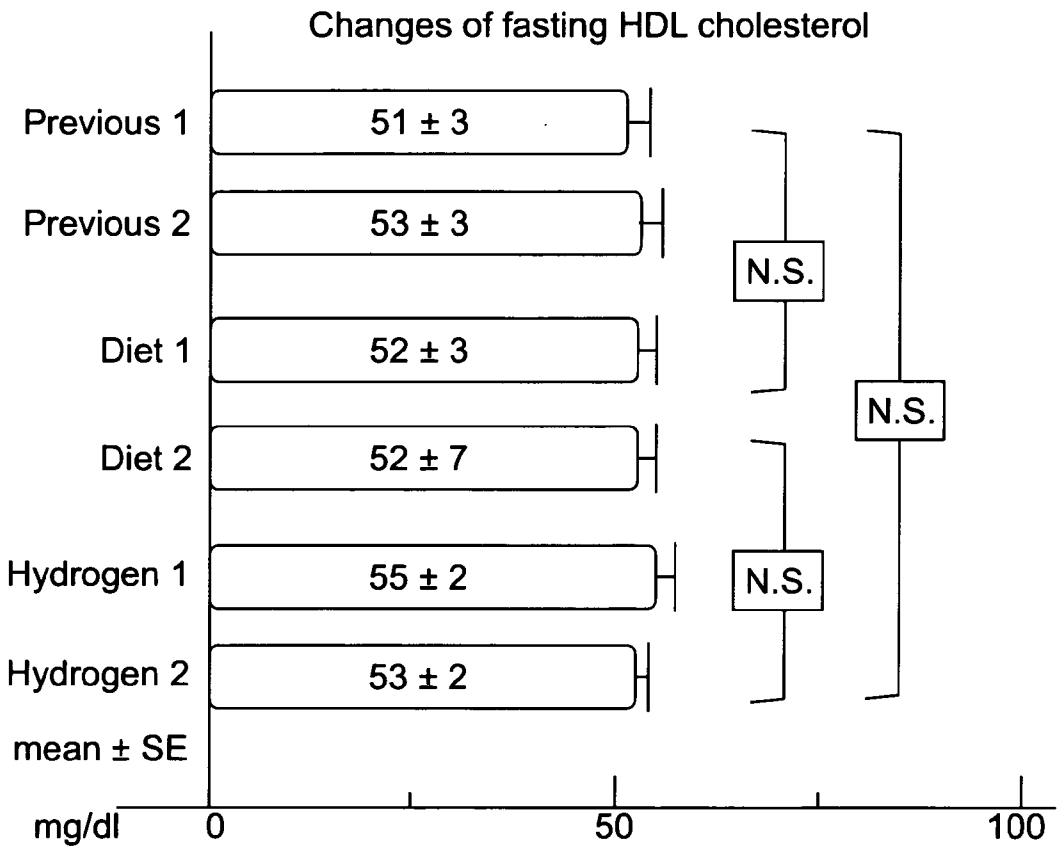

Changes of fasting HDL cholesterol
Previous 1
51 ± 3
Previous 2
53 ± 3
Diet 1
52 ± 3
Diet 2
52 ± 7
Hydrogen 1
55 ± 2
Hydrogen 2
53 ± 2
mean ± SE
mg/dl
0
50
100
N.S.
N.S.
N.S.

Figure 30

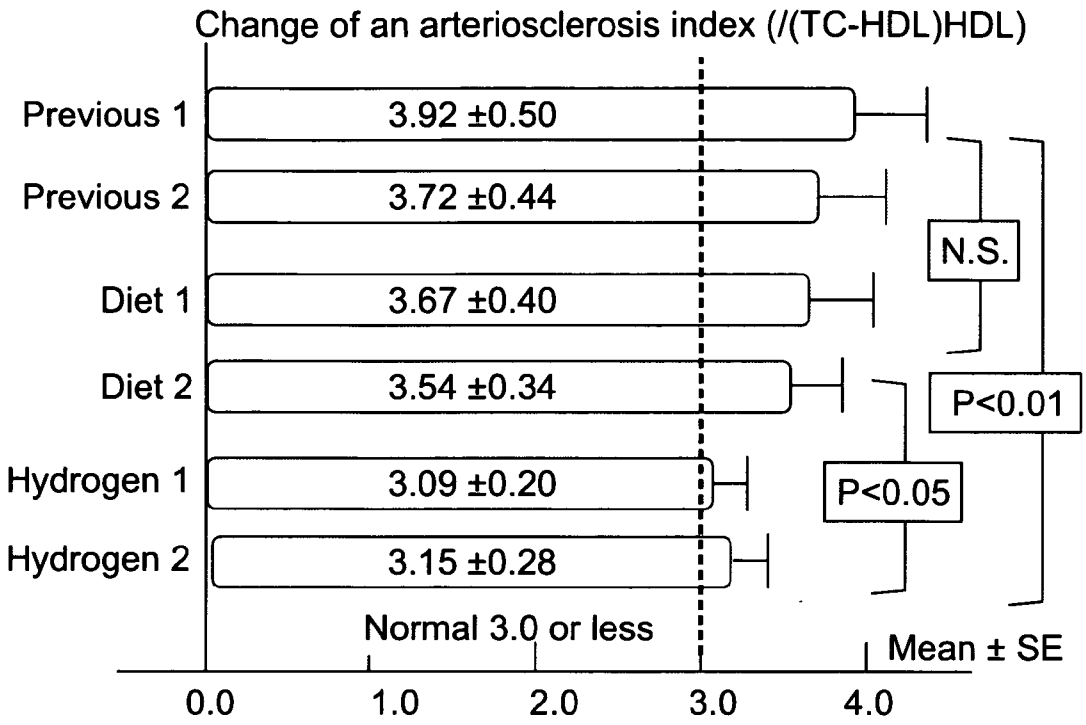


Figure 31

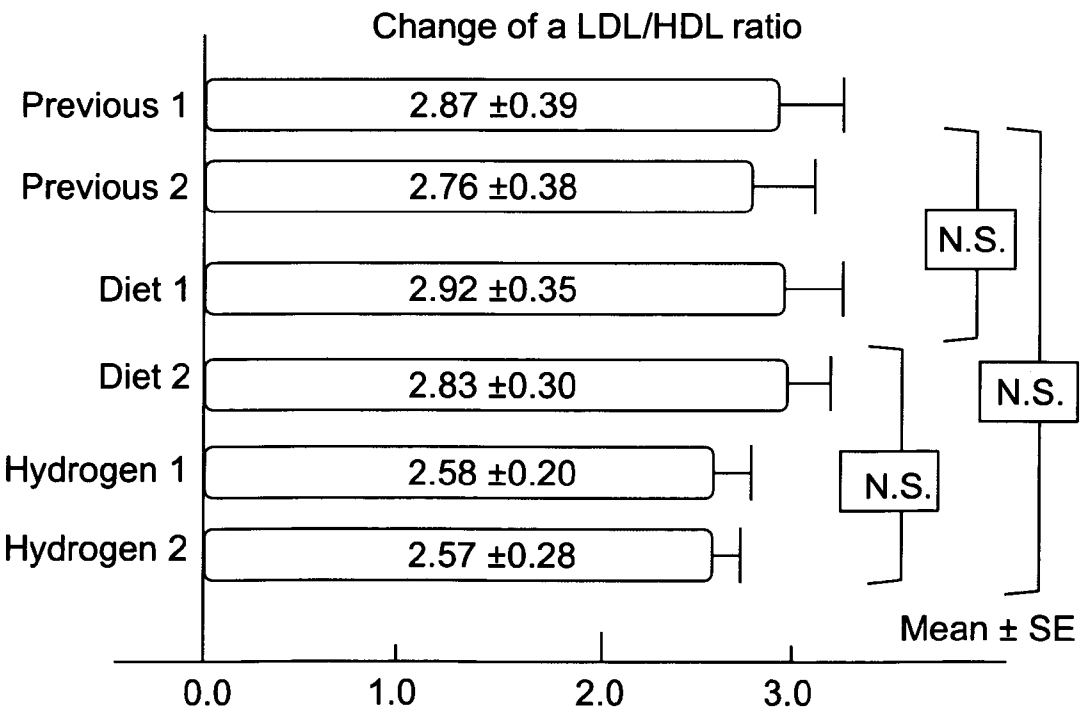


Figure 32

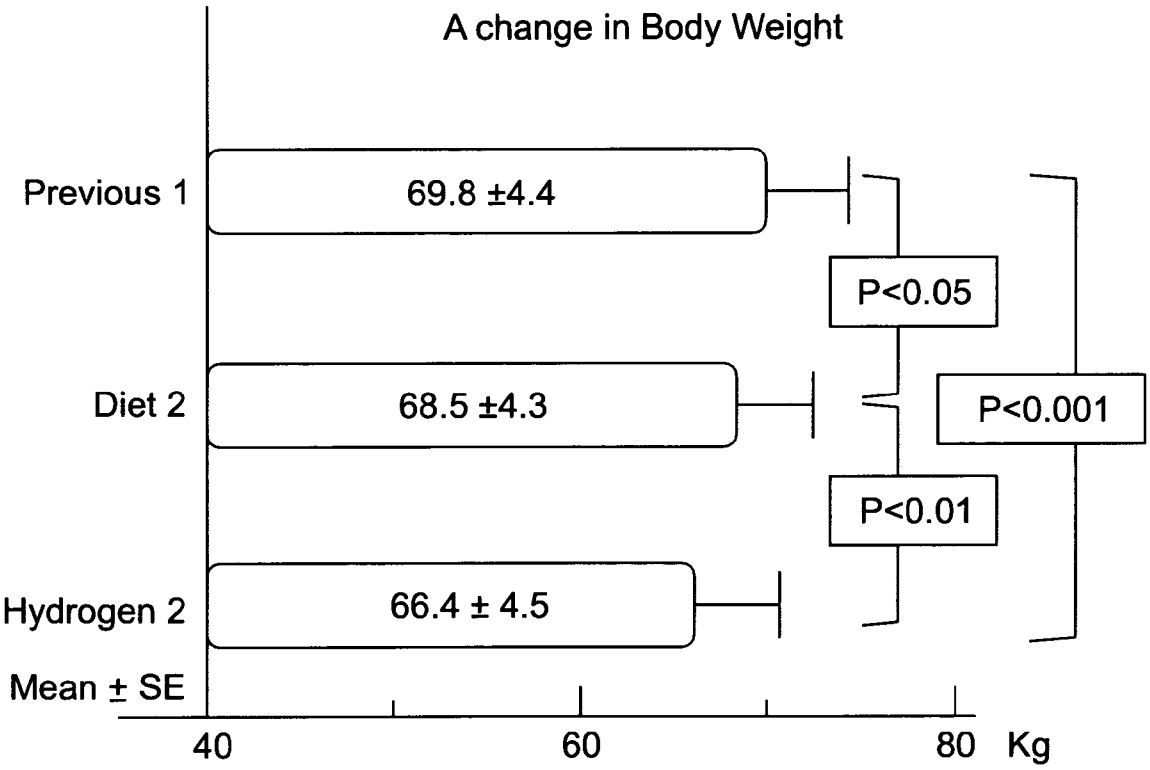

A change in Body Weight
Previous 1
69.8 ±4.4
P<0.05
Diet 2
68.5 ±4.3
P<0.001
P<0.01
Hydrogen 2
66.4 ± 4.5
Mean ± SE
40
60
80
Kg

Figure 33

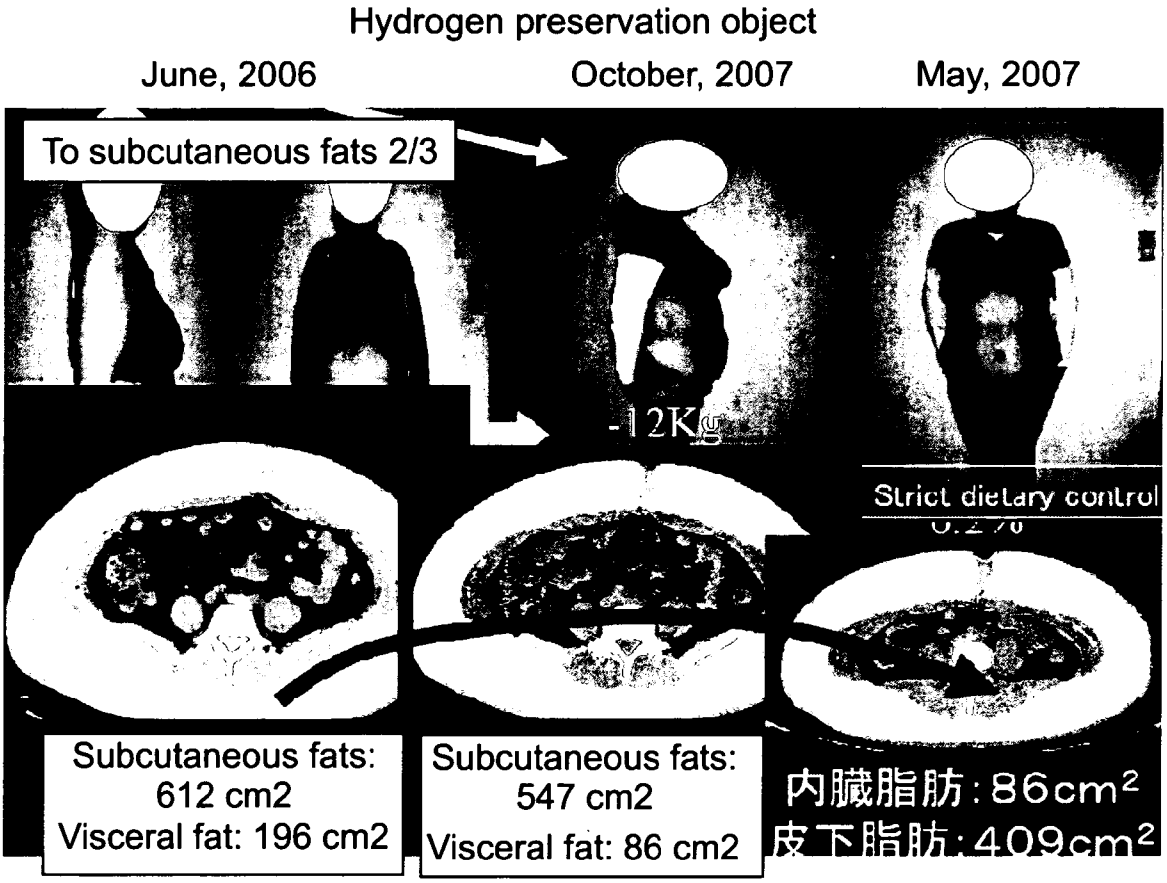

Hydrogen preservation object
June, 2006
October, 2007
May, 2007
To subcutaneous fats 2/3
-12Kg
Strict dietary control
Subcutaneous fats:
612 cm2
Visceral fat: 196 cm2
Subcutaneous fats:
547 cm2
Visceral fat: 86 cm2
内臓脂肪:86cm²
皮下脂肪:409cm²

Figure 34

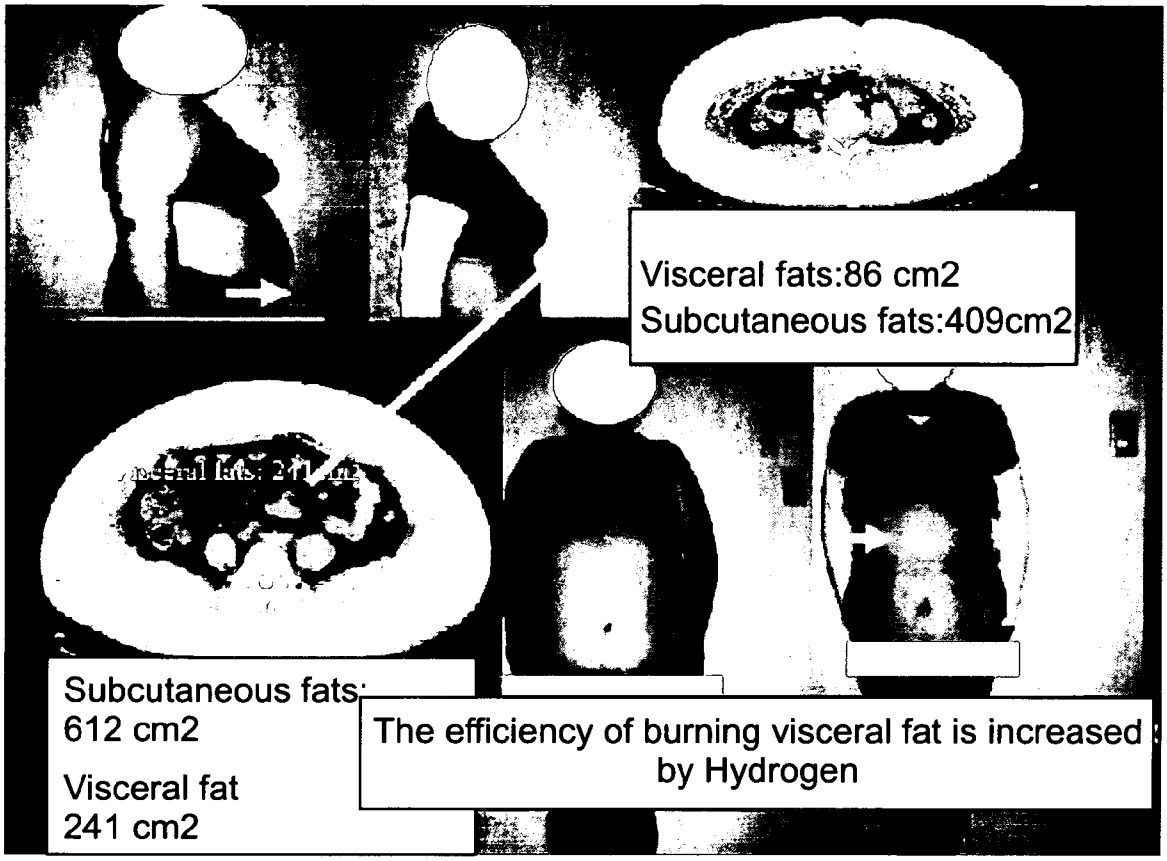


Figure 35

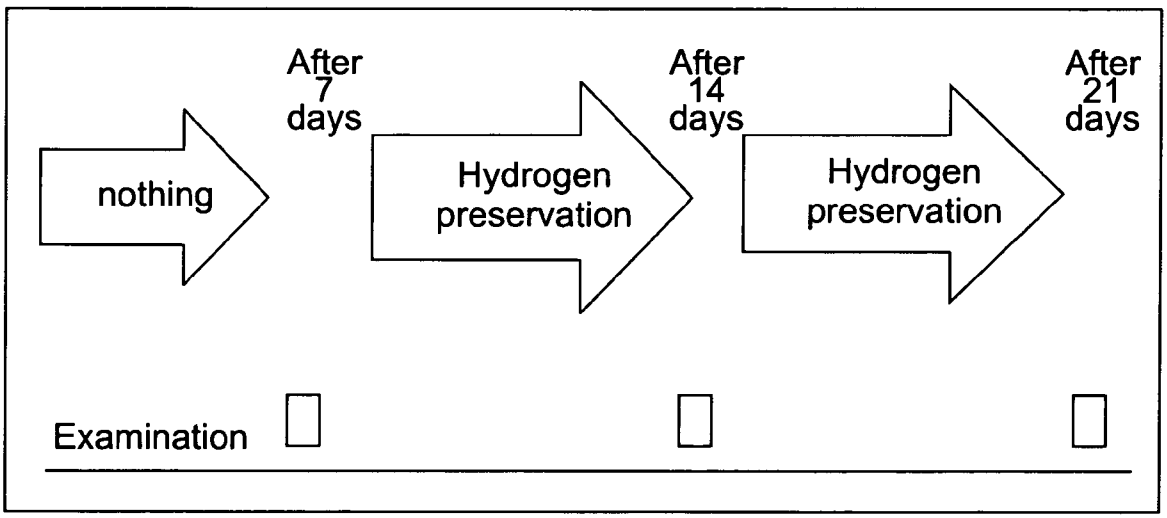


Figure 36

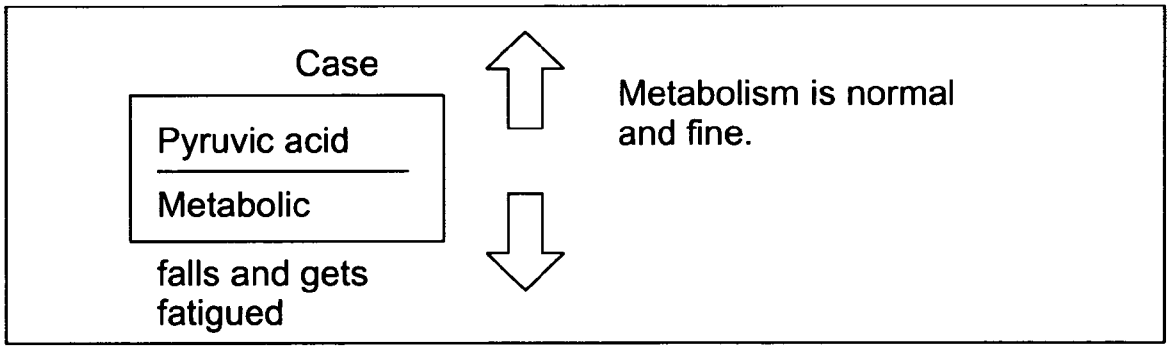


Figure 37

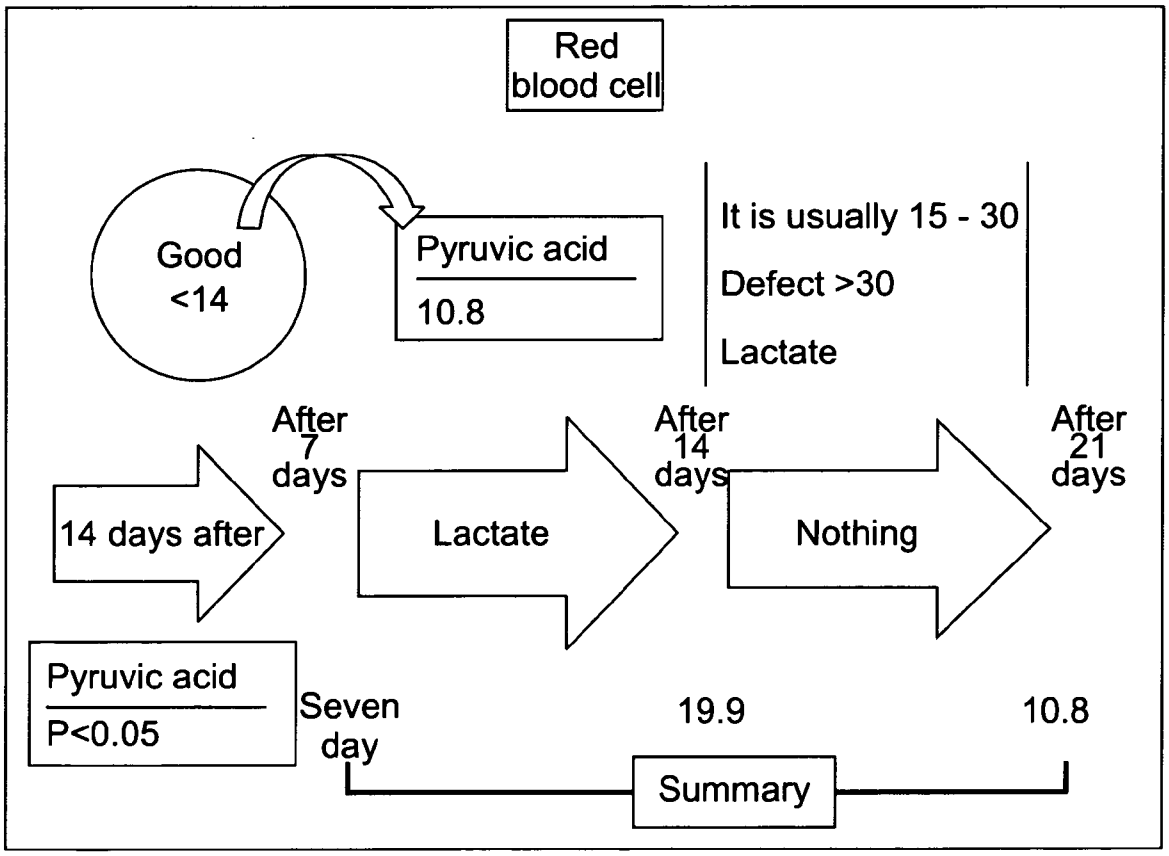
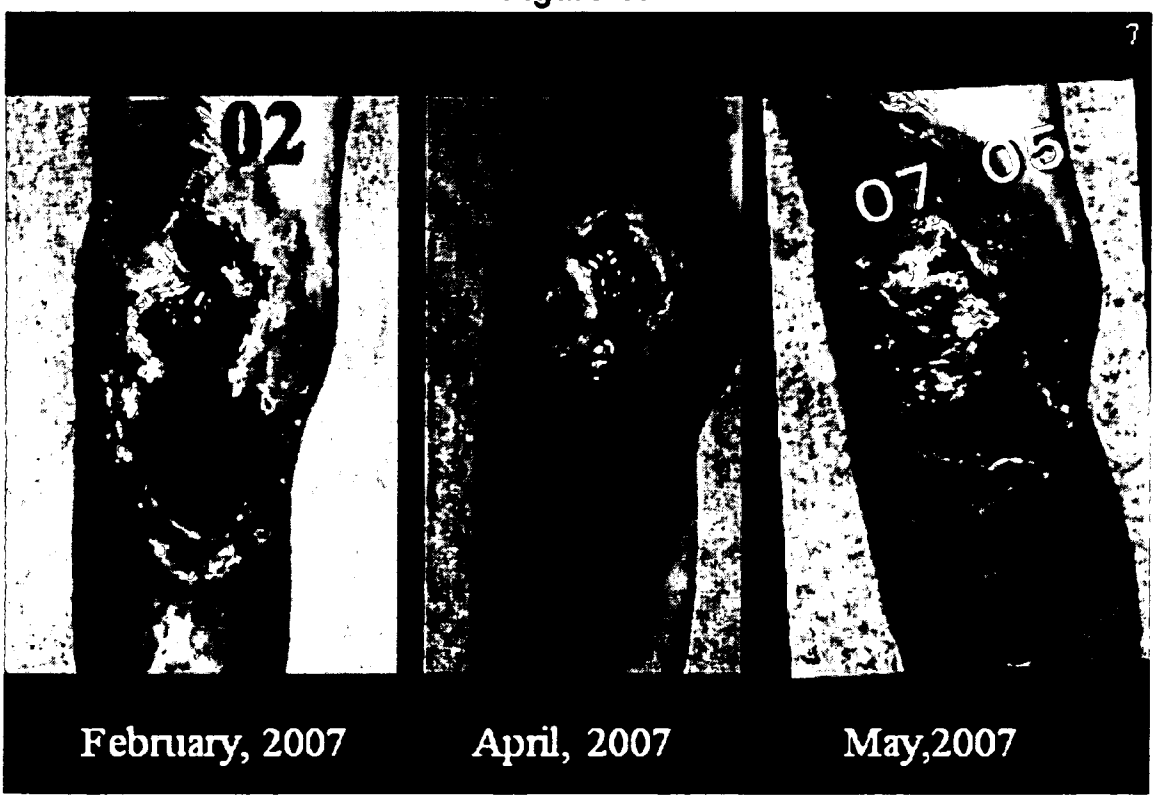


Figure 38

Figure 39

Figure 40



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2011/056184

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K31/05 A61K31/122 A61K31/47 A61K31/4709 A61K33/00
A61K33/06 A61K33/14 A61K35/00 A61P29/00 A61P3/04
A61P3/06 A61P3/10 A61P5/00 A61P9/12 A61P15/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, BIOSIS, EMBASE, BEILSTEIN Data, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 236 144 A1 (MIZ CO LTD [JP]) 6 October 2010 (2010-10-06)	1-4, 7-11,17, 27, 30-37, 39-47, 49-52, 54-56,62
Y	pages 29, 30; claims 1-8,14 page 5, paragraphs 34,35 page 6, paragraph 53 page 7, paragraph 55 page 9, paragraph 74	7-15,18, 30-40, 42-45, 48, 50-55, 58,60,61

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 February 2012	07/03/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Opravz, Petra

8

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 2004 330028 A (SAN WAAKU KK) 25 November 2004 (2004-11-25) claims 1-6 page 6, paragraphs 30,31 page 7, paragraph 37	1,2,4,7, 8,11,27, 30, 36-38, 50,54, 55,62
X	NAKAO ATSUNORI ET AL: "Effectiveness of hydrogen rich water on antioxidant status of subjects with potential metabolic syndrome-an open label pilot study.", JOURNAL OF CLINICAL BIOCHEMISTRY AND NUTRITION MAR 2010 LNKD- PUBMED:20216947, vol. 46, no. 2, March 2010 (2010-03), pages 140-149, XP002655319, ISSN: 1880-5086 abstract page 140, left-hand column	1,2,4,7, 11,27, 30,36, 37,50, 53-55,62
X	FUJITA KYOTA ET AL: "Hydrogen in drinking water reduces dopaminergic neuronal loss in the 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine mouse model of Parkinson's disease.", PLOS ONE 2009 LNKD- PUBMED:19789628, vol. 4, no. 9, 2009, page E7247, XP002655320, ISSN: 1932-6203 page 2, left-hand column page 3	1,2,4,7, 11,27, 30,45, 48,54, 55,62
X	JP 2005 245265 A (SOZOTEKI SEIBUTSU KOGAKU KENKY) 15 September 2005 (2005-09-15)	26
Y	the whole document	18
X	WO 2010/095279 A1 (INST CREATIVE BIOTECHNOLOGY LT [JP]; OIKAWA TANEAKI [JP]) 26 August 2010 (2010-08-26)	6,16,21, 22,28,29
Y	the whole document	7-15, 30-40, 42-45, 48, 50-55, 58,60,61

8

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2011/056184

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 2236144 A1	06-10-2010	CN 101951929 A	19-01-2011
		EP 2236144 A1	06-10-2010
		US 2010272789 A1	28-10-2010
		WO 2009084743 A1	09-07-2009
JP 2004330028 A	25-11-2004	NONE	
JP 2005245265 A	15-09-2005	JP 4404657 B2	27-01-2010
		JP 2005245265 A	15-09-2005
WO 2010095279 A1	26-08-2010	NONE	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2011/056184

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

1-4, 6, 16-18, 21, 22, 26-29, 56, 58, 60, 61(completely); 7-15, 30-55
62(partially)

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-4(completely); 7-11, 30-55, 62(partially)

   A hydrogen emitting composition for pharmaceutical use comprising a magnesium compound.

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2. claims: 12-15, 30-55, 62(all partially)

   A hydrogen emitting composition according to claims 1-4 also comprising CoQ10 or an analogue thereof.

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3. claims: 16-18, 26, 27, 56(completely); 62(partially)

   A method for manufacturing a magnesium hydride or a magnesium metal composition as defined in the present claims 16-18, 26 and 27.

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4. claims: 5, 19, 20, 23-25, 57, 59(completely); 7-15, 30-55, 62(partially)

   A composition for pharmaceutical use wherein the composition comprises a magnesium hydride, a calcium hydride and a halogen chloride, preferably, NaCl, all preferably in powder form; a method for manufacturing said composition as defined in the present claims 19, 20, 23-25; and their use as defined in the present claims 30-55, 57, 59.

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5. claims: 6, 21, 22, 28, 29, 58, 60, 61(completely); 7-15, 30-55, 62(partially)

   A composition for pharmaceutical use wherein the composition comprises magnesium metal, preferably in powder form, magnetic ceramic balls and activated carbon, preferably in powder form; a method for manufacturing said composition as defined in the present claims 21, 22, 28, 29; their use as defined in the present claims 30-55, 58, 60, and kit as defined in claim 61.
