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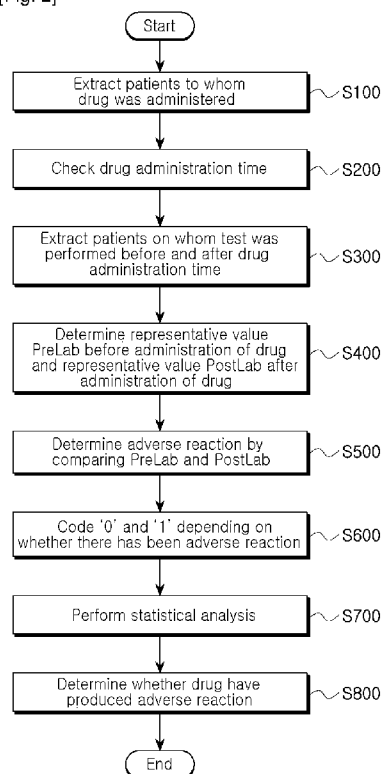
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(54) Title: METHOD OF DETECTING ADVERSE REACTION TO DRUG USING ELECTRONIC MEDICAL RECORD, METHOD OF DETECTING ADVERSE REACTION TO INTERVENTION, AND METHOD OF DETECTING ADVERSE REACTION TO DRUG OR INTERVENTION USING ELECTRONIC MEDICAL RECORD AND ELECTROCARDIOGRAM DATA

[Fig. 2]

(57) Abstract: Disclosed herein is a method of detecting an adverse reaction to a drug using an Electronic Medical Record (EMR). The method includes the steps of (a) determining a drug and a test; (b) selecting patients to whom the drug was administered from an EMR database; (c) checking a first administration time t_i when the drug was first administered to the selected patients; (d) extracting patients on whom the test was performed before and after the first administration time t_i from the selected patients; (e) determining a representative value PreLab before the administration of the drug and a representative value PostLab after the administration of the drug, from among results of the test for the extracted patients based on the first administration time t_i ; and (f) determining whether the drug have produced the adverse reaction by performing statistical verification on the representative values.



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Description

Title of Invention: METHOD OF DETECTING ADVERSE REACTION TO DRUG USING ELECTRONIC MEDICAL RECORD, METHOD OF DETECTING ADVERSE REACTION TO INTERVENTION, AND METHOD OF DETECTING ADVERSE REACTION TO DRUG OR INTERVENTION USING ELECTRONIC MEDICAL RECORD AND ELECTRO-CARDIOGRAM DATA

Technical Field

- [1] This application is supported by Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education, Science and Technology (2009-0068810 and 2010-0028631).
- [2] The present invention relates, in general, to a method of detecting an adverse reaction to a drug using an Electronic Medical Record (EMR). More particularly, the present invention relates to a method of detecting an adverse reaction to a drug using an EMR, including the steps of selecting a patient to which the drug was administered from an EMR database; checking a first administration time when the drug was first administered; determining a representative value PreLab before the administration of the drug and a representative value PostLab after the administration of the drug on the basis of the first administration time; and determining whether the drug has produced the adverse reaction using statistical verification.
- [3]
- [4] Furthermore, the present invention relates to a method of detecting an adverse reaction to an intervention using an EMR. More particularly, the present invention relates to a method of detecting an adverse reaction to an intervention using an EMR, including the steps of selecting a patient on which the intervention was performed from an EMR database; checking a first intervention time when the intervention was first performed; determining a representative value PreLab before the intervention and a representative value PostLab after the intervention on the basis of the first intervention time; and determining whether the intervention has produced the adverse reaction using statistical verification.
- [5] Furthermore, the present invention relates to a method of detecting an adverse reaction to a drug and an intervention using an EMR and electrocardiogram (ECG) data. More particularly, the present invention relates to a method of detecting an adverse reaction to a drug and an intervention using an EMR and ECG data, including

the steps of selecting patients to whom the drug was administered or patients on whom the intervention was performed from an EMR database; checking a first time when the drug was first administered or when the intervention was first performed; determining a representative value PreECG before the administration of the drug and a representative value PostECG after the administration of the drug or a representative value PreECG' before the intervention and a representative value PostECG' after the intervention on the basis of the first time; and determining whether the drug or intervention has produced the adverse reaction using statical verification.

[6]

Background Art

[7] With the recent introduction of an EMR worldwide, various pieces of prescription information and intervention information and ECG test results are accumulating in geometrical progression. The present invention is intended to provide a method of detecting adverse reactions to a drug and an intervention using EMRs.

[8] Conventional methods of detecting adverse reactions to drugs include spontaneous reporting system and a method using test result data (a data mining scheme).

[9] In the case of the spontaneous reporting system, the reporting rate is very low, and a report is rarely made even when there has been an adverse reaction to a drug.

[10] In the case of the data mining scheme, voluntary report data that may be called secondary data is utilized. There is a limit to the detection of various adverse reactions to various drugs because of the shortages in source data and patient cases. Moreover, the process of defining conditions on test results (e.g., no intervention of some other drug) and finding only cases satisfying the conditions requires a lot of time and effort, such as the participation of an expert and the review of charts. Accordingly, it is practically impossible to check various adverse reactions to various drugs.

[11] Furthermore, unlike the methods of verifying adverse reactions to drugs based on spontaneous reporting system and the method using test results data (a data mining scheme), research into adverse reactions to intervention and a method of statistically verifying adverse reactions to interventions has not yet been actively carried out.

[12] Furthermore, the conventional methods of detecting adverse reactions to drugs are also problematic in that in the case of the spontaneous reporting system, the reporting rate is very low and a report may not be made even when there has been an adverse reaction, and that in case of the data mining scheme, various adverse reactions are undetected because of the shortages in source data and patient cases.

[13]

Disclosure of Invention

Technical Problem

- [14] Accordingly, the present invention has been made keeping in mind the above problems occurring in the prior art, and an object of the present invention is to detect various adverse reactions to various drugs using the existing EMR database and provide statistical significance, without the participation of an expert, thereby being helpful to pharmacoepidemiology and the safety of patients.
- [15] Another object of the present invention is to detect various adverse reactions to various interventions using the existing EMR database and provide statistical significance, without the participation of an expert, thereby being helpful to the intervention of epidemiology and the safety of patients.
- [16] A further object of the present invention is to detect various adverse reactions to various drugs or various interventions using the existing EMR database and ECG data and provide statistical significance, without the participation of an expert, thereby being helpful to the intervention of epidemiology and the safety of patients.

[17]

Solution to Problem

- [18] In order to accomplish one of the above objects, the present invention provides a method of determining an adverse reaction to a drug by extracting data related to a drug, patients, a test, and test results, which are selected by a user, from the existing EMR database.
- [19] In detail, in order to accomplish one of the above objects, the present invention provides a method of detecting an adverse reaction to a drug using an Electronic Medical Record (EMR), the method including the steps of (a) determining a drug for which an adverse reaction is to be checked and a test for detecting the adverse reaction; (b) selecting patients to whom the drug was administered from an EMR database; (c) checking a first administration time t_i when the drug was first administered to the selected patients; (d) extracting patients on whom the test was performed before and after the first administration time t_i from the selected patients; (e) determining a representative value PreLab before the administration of the drug and a representative value PostLab after the administration of the drug, from among results of the test for the extracted patients based on the first administration time t_i ; and (f) determining whether the drug have produced the adverse reaction by performing statistical verification on the representative value PreLab before the administration of the drug and the representative value PostLab after the administration of the drug.
- [20] The step (e) may include the step of, if the test determines that there has been an adverse reaction if the results of the test are lower than a specific reference numerical value, determining a minimum value, selected from among the results of the test before the drug was administered to the extracted patients, to be the representative value

PreLab before the administration of the drug, and determining a minimum value, selected from among the results of the test after the drug was administered to the extracted patients, to be the representative value PostLab after the administration of the drug, based on the first administration time.

- [21] The step (e) may include the step of, if the test determines that there has been an adverse reaction if the results of the test are higher than a specific reference numerical value, determining a maximum value, selected from among the results of the test before the drug was administered to the extracted patients, to be the representative value PreLab before the administration of the drug, and determining a maximum value, selected from among the results of the test after the drug was administered to the extracted patients, to be the representative value PostLab after the administration of the drug, based on the first administration time.
- [22] The step (e) may include the steps of (e1) converting the results of the test into numerical values; and (e2) determining the representative value PreLab before the administration of the drug and the representative value PostLab after the administration of the drug, from among the numerical values of the test for the extracted patients, based on the first administration time t_i .
- [23] At the step (f), the statistical verification may include one or more selected from the group consisting of a paired T-test and a McNemar test.
- [24] The step (f) may include the steps of (f1) determining whether each of the patients experiences an adverse reaction using the representative value PreLab before the administration of the drug and the representative value PostLab after the administration of the drug; (f2) coding different numerical values for a normal state and for the adverse reaction based on results of the determination; and (f3) determining whether the drug has produced the adverse reaction by comparing frequencies of the coded adverse reaction.
- [25] The step (a) may include the step of selecting a patient group which is an object of whether there has been an adverse reaction; and the step (b) may include selecting the patients to whom the drug was administered from the patient group selected from the EMR database.
- [26] The step (b) may include the steps of copying data of the EMR database to a data warehouse; and selecting the patients to whom the drug was administered from the data copied to the data warehouse.
- [27] In order to accomplish another of the above objects, the present invention provides a method of determining an adverse reaction to an intervention by extracting data related to an intervention, patients, a test, and test results, which are selected by a user, from the existing EMR database.
- [28] In detail, in order to accomplish another of the above objects, the present invention

provides a method of detecting an adverse reaction to an intervention using an EMR, the method including the steps of (a) determining intervention for which an adverse reaction is to be checked and a test for detecting the adverse reaction; (b) selecting patients on which the intervention was performed from an EMR database; (c) checking a first intervention time t_i when the intervention was first performed on the selected patients; (d) extracting patients on whom the test was performed before and after the first intervention time t_i from the selected patients; (e) determining a representative value PreLab before the intervention and a representative value PostLab after the intervention, from among results of the test for the extracted patients, based on the first intervention time t_i ; and (f) determining whether the intervention has produced the adverse reaction by performing statistical verification on the representative value PreLab before the intervention and the representative value PostLab after the intervention.

- [29] The step (e) may include the step of, if the test determined that there has been an adverse reaction if the results of the test are lower than a specific reference numerical value, determining a minimum value, selected from among the results of the test before the intervention was performed on the extracted patients, to be the representative value PreLab before the intervention, and determining a minimum value, selected from among the results of the test after the intervention was performed on the extracted patients, to be the representative value PostLab after the intervention, based on the first intervention time.
- [30] The step (e) may include the step of, if the test determines that there has been an adverse reaction if the results of the test are higher than a specific reference numerical value, determining a maximum value, selected from among the results of the test before the intervention was performed on the extracted patients, to be the representative value PreLab before the intervention, and determining a maximum value, selected from among the results of the test after the intervention was performed on the extracted patients, to be the representative value PostLab after the intervention, based on the first intervention time.
- [31] In order to accomplish another of the above objects, the present invention provides a method of determining an adverse reaction to a drug or intervention by extracting data related to drugs or an intervention, patients, and ECG test results, which are selected by a user, from the existing EMR database.
- [32] In detail, in order to accomplish another of the above objects, the present invention provides a method of detecting an adverse reaction to a drug using EMR and electrocardiogram (ECG) data, the method including the steps of (a) determining drug for which an adverse reaction is to be checked; (b) selecting patients to whom the drug was administered from an EMR database; (c) checking a first time t_i when the drug

was first administered to the selected patients; (d) extracting patients on whom an ECG test was performed before and after the first time t_i from the selected patients; (e) determining a representative value PreECG before the administration of the drug and a representative value PostECG after the administration of the drug, from among results of the ECG test for the extracted patients, based on the first time t_i ; and (f) determining whether the drug have produced the adverse reaction by performing statistical verification on the representative value PreECG before the administration of the drug and the representative value PostECG after the administration of the drug.

[33] The step (e) may include the step of, if the ECG test determines that there has been an adverse reaction if the results of the test are lower than a specific reference numerical value, determining a minimum value, selected from among the results of the ECG test before the drug was administered to the extracted patients, to be the representative value PreECG before the administration of the drug, and determining a minimum value, selected from among the results of the ECG test after the drug was administered to the extracted patients, to be the representative value PostECG after the administration of the drug, based on the first time.

[34] The step (e) may include the step of, if the ECG test determined that there has been an adverse reaction if the results of the test are higher than a specific reference numerical value, determining a maximum value, selected from among the results of the ECG test before the drug was administered to the extracted patients, to be the representative value PreECG before the administration of the drug, and determining a maximum value, selected from among the results of the ECG test after the drug was administered to the extracted patients, to be the representative value PostECG after the administration of the drug, based on the first time.

[35] Additionally, in order to accomplish the above objects, the present invention provides a method of detecting an adverse reaction to an intervention using EMR and ECG data, the method including the steps of (a) determining an intervention for which an adverse reaction is to be checked; (b) selecting patients to whom the intervention has been performed from an EMR database; (c) checking a first time t_i when the intervention was first performed on the selected patients; (d) extracting patients on whom an ECG test was performed before and after the first time t_i from the selected patients; (e) determining a representative value PreECG' before the intervention and a representative value PostECG' after the intervention, from among results of the ECG test for the extracted patients, based on the first time t_i ; and (f) determining whether the intervention has the adverse reaction by performing statistical verification on the representative value PreECG' before the intervention and the representative value PostECG' after the intervention.

[36]

Advantageous Effects of Invention

- [37] The above method of solving the problem enables various adverse reactions to various drugs to be detected using the existing EMR database even without the participation of an expert. In particular, the accuracy of results is increased thanks to the accumulation of data in the EMR database, and a variety of statistical results may help a user make additional determinations.
- [38] In particular, since statistical processing may be performed objectively and rapidly, various adverse reactions of lots of drugs can be verified rapidly and accurately, as compared with the conventional spontaneous reporting system and data mining scheme.
- [39] The above method of solving the problem enables various adverse reactions to various interventions to be detected using the existing EMR database without the participation of an expert. In particular, the accuracy of results is increased according to the accumulation of data in the EMR database, and a variety of statistical results may help a user make additional determinations.
- [40] In particular, since statistical processing may be performed objectively and rapidly, various adverse reactions to various interventions can be verified rapidly and accurately.
- [41] The above method of solving the problem enables various adverse reactions to various drugs or various interventions to be detected using the existing EMR database and ECG data even without the participation of an expert using the above solving means. In particular, the accuracy of results is increased thanks to the accumulation of data in the EMR database, and a variety of statistical results may help a user make additional determinations.
- [42] In particular, since statistical processing may be performed objectively and rapidly, various adverse reactions to various drugs and various interventions can be verified rapidly and accurately, as compared with the conventional spontaneous reporting system and data mining scheme.

[43]

Brief Description of Drawings

- [44] The above and other objects, features, and advantages of the present invention will be more clearly understood from the following detailed description taken in conjunction with the accompanying drawings, in which:
- [45] FIG. 1 is a schematic diagram showing a system for detecting an adverse reaction to a drug according to a first embodiment of the present invention;
- [46] FIG. 2 is a flowchart illustrating a method of detecting an adverse reaction to a drug according to a first embodiment of the present invention;

- [47] FIG. 3 is an example illustrating the method of detecting an adverse reaction to a drug according to the first embodiment of the present invention, and a test value versus time graph in which test values and time are set for two axes;
- [48] FIG. 4 is a flowchart illustrating a method of detecting an adverse reaction to an intervention according to a second embodiment of the present invention;
- [49] FIG. 5 is a schematic diagram showing ECG data according to a third embodiment of the present invention; and
- [50] FIG. 6 is a flowchart illustrating a method of detecting an adverse reaction to a drug according to a third embodiment of the present invention.

[51]
[52]

Best Mode for Carrying out the Invention

- [53] It is to be understood that the term drug refers to any material which can be administered, such as by eating, in paste or as an injection, for the purpose of treating, checking, or preventing the physical or psychological state of a target patient.
- [54] The term test refers to any type of examination which is conducted under specific conditions in order to check the physical or psychological state of a target patient. In the present invention, in order to check an adverse reaction to a drug, a specific test is selected and results of the specific test are statistically used. The results of the test are called test result or test values.
- [55] It is to be understood that the term patient refers to any person whose records have been stored in an EMR database. The patient does not necessarily have to be an object which is in a physically or psychologically abnormal state, but is a person whose drug administration records or test records or both are present in the EMR database and whose adverse reaction to a drug can be checked.
- [56] It is to be understood that the term statistical verification refers to any type of method of processing and verifying a lot of data in order to check a specific purpose (here, to check an adverse reaction to a drug). For example, the statistical verification may include a paired T-test and a McNemar test, but is not limited thereto.
- [57] It is to be understood that the term intervention refers to any action which is performed for the purpose of treating, checking, or preventing the physical or psychological state of a target patient.
- [58] The present invention will be described in detail below with reference to the drawings.
- [59] First embodiment: system and method for detecting an adverse reaction to a drug
- [60] The system for detecting an adverse reaction to a drug according to the first embodiment of the present invention will now be described with reference to FIG. 1.

- [61] The system for detecting an adverse reaction to a drug according to the first embodiment of the present invention includes an EMR database 10, an Adverse Drug Reaction (ADR) management unit 100, a suspect drug selector 200, a search space reducer 300, an ADR detection algorithm 400, a statistical analysis system 500, and a report system 600.
- [62] The system for detecting an adverse reaction to a drug according to the first embodiment of the present invention employs the EMR database 10 which was constructed previously. The EMR database 10 may be a database established using any conventional method. It is preferred that the EMR database 10 include drug prescription information and various pieces of test information about patients.
- [63] Furthermore, a test for an adverse reaction to a drug may be performed using the EMR database 10. If data is copied to an additional data warehouse (not shown) and a test for an adverse reaction to a drug is performed using the data warehouse, load is not exerted on the existing EMR database 10. The data warehouse may be of any type which can store and load data. In an embodiment, it may be a server.
- [64] A user may select a test from which an adverse reaction to a drug can be detected, and control test numerical values (i.e., criteria) through the ADR management unit 100. Here, the normal and abnormal numerical values of test results are converted into signals and stored in the ADR signal database 110. The ADR management unit 100 may provide a user with all the test lists, test names, and test numerical values. A user may modify, delete, and insert the signals using a separate input unit.
- [65] A user may select a drug to be monitored using the suspect drug selector 200. The suspect drug selector 200 may provide the entire drug list to a user, and provide a separate search function to the user.
- [66] A user may select a specific patient group on the basis of data of the EMR database 10 using the search space reducer 300. For example, a user may select a group of patients having a specific sex, age and administration period from among patients to whom a drug was administered.
- [67] The ADR detection algorithm 400 functions to search test results before and after the administration of the drug and to set data for the test results. The ADR detection algorithm 400 may include a first administration time check unit, a test check unit, and a representative value selection unit.
- [68] The first administration time check unit checks a date on which the corresponding drug was first administered to a patient (hereinafter referred to as a 'first administration time'). When the test was performed before and after the first administration time on the basis of the checked drug administration time, whether there has been an adverse reaction can be checked.
- [69] Accordingly, the test check unit extracts a target patient on which a test was

performed by checking whether the corresponding test was performed before and after the drug administration time. In this process, the target patient may be extracted from a group of patients previously selected by the search space reducer 300.

[70] The representative value selection unit extracts test results before and after the drug administration time, and selects representative values from the test results.

[71] The statistical analysis system 500 may perform statistical verification on the comparison of the averages before and after the administration of the drug (paired T-test) or the comparison of abnormal appearance frequencies (McNemar test) using data set by the ADR detection algorithm 400, while operating in conjunction with a statistical packet. Statistical verification of any method, other than the paired T-test and the McNemar test, may also be performed.

[72] In an embodiment, an adverse reaction to a drug can be checked by performing a paired T-test for comparing the total average of representative values before the administration of the drug and the total average of representative values after the administration of the drug. For example, in the case of a White Blood Cell (WBC) test indicative of a leukocyte numerical value, if the WBC has a low numerical value, it may be said that an adverse reaction exists. If, as a result of the paired T-test, the numerical value of the WBC is statistically reduced to some extent after the drug has been administered, an adverse reaction is determined to exist in the corresponding drug.

[73] In another embodiment, whether a patient experiences an adverse reaction to a drug may be checked by comparing a representative value before the administration of the drug and a representative value after the administration of the drug for each patient. For example, '0' may be coded for a normal state, and '1' may be coded for an adverse reaction. Whether the drug has an adverse reaction may be finally determined by performing a McNemar test for the numerical values.

[74] The report system 600 may store and output statistical analysis results, obtained by the statistical analysis system 500, and analysis results, such as the number of target analysis patients.

[75] A method of detecting an adverse reaction to a drug according to the first embodiment of the present invention will now be described with reference to FIGS. 2 and 3. It is to be noted that FIG. 2 shows the case where a paired T-test and a McNemar test are performed at the same time.

[76] A user determines a drug for which an adverse reaction is to be checked, a target patient group, and a test. The drug for which an adverse reaction is to be checked may be determined by the suspect drug selector 200. The target patient group may be determined by the search space reducer 300 on the basis of various parameters. The test may be determined by the ADR management unit 100.

[77] Thereafter, the system extracts only patients to whom the drug was administered

from the EMR database 10 at step S100. In the process of extracting the patients to whom the drug was administered, the system checks the time when the drug was first administered (i.e., a first administration time) for each patient at step S200.

[78] In addition to the first administration time, a drug administration period and a drug administration end time may be required depending on the type of test or the type of drug. In this case, the system may check all the times.

[79] Referring to FIG. 3, t_0 indicates the EMR start time of a patient, and t_1 indicates the EMR end time of the patient. Here, t_i is the first administration time, and t_e is the drug administration end time. In general, the first administration time t_i is used, but the drug administration end time t_e may be used depending on circumstances. The case where the first administration time t_i is used will now be described as an example.

[80] Thereafter, at step S300, patients on whom the determined test were performed before and after the first administration time t_i are extracted from the patients extracted at step S100.

[81] A representative value PreLab before the administration of the drug and a representative value PostLab after the administration of the drug are determined at step S400 by checking the results A1 to A18 of the test performed on the patients extracted at step S300. Which values will become the representative values are quite different depending on the corresponding test.

[82] For example, in the case where a low numerical value corresponds to an adverse reaction as in the WBC, a minimum value A8 from among the test results A1 to A9 before the administration of the drug may be determined to be the representative value PreLab before the administration of the drug, and a minimum value A16 from among the test results A10 to A18 after the administration of the drug may be determined to be the representative value PostLab after the administration of the drug.

[83] In contrast, in the case where a high numerical value corresponds to an adverse reaction as in a Creatinine numerical value Cr indicative of a renal function, a maximum value A7 from among the test results A1 to A9 before the administration of the drug may be determined to be the representative value PreLab before the administration of the drug, and a maximum value A17 from among the test results A10 to A18 after the administration of the drug may be determined to be the representative value PostLab after the administration of the drug.

[84] In another embodiment, in the case where some or all of test results are not numerical values, the test results need to be converted into numerical values. For example, in the case of urine protein, test results may be recorded in the form of Neg, Trace, 1+, 2+, and 3+. Neg, Trace, 1+, 2+, and 3+ are converted into numerical values 0, 0, 1, 2, and 3, respectively, and then a representative value PreLab before the administration of the drug and a representative value PostLab after the administration of the drug are de-

terminated.

- [85] Whether an adverse reaction has been produced by the drug is determined by performing statistical verification on the representative value PreLab before the administration of the drug and the representative value PostLab after the administration of the drug at step S500.
- [86] In an embodiment, in accordance with the paired T-test, the total averages of the representative value PreLab before the administration of the drug and the representative value PostLab after the administration of the drug of the patients are compared. If, as a result of the comparison, the representative value PostLab after the administration of the drug corresponds to predetermined adverse reaction criteria, the corresponding drug is determined to have produced an adverse reaction.
- [87] In another embodiment, in accordance with the McNemar test, whether a patient experiences an adverse reaction to a drug may be checked by comparing a representative value PreLab before the administration of the drug and a representative value PostLab after the administration of the drug for each patient. Thereafter, '0' and '1' may be coded depending on whether there has been an adverse reaction at step S600. Whether the drug has produced an adverse reaction may be finally determined at step S800 by performing statistical analysis, such as frequency analysis, on the values at step S700.
- [88] Here, according to the user settings, in the case where an adverse reaction is determined to have been produced by the drug using both the paired T-test and the McNemar test, the drug may be determined to have produced an adverse reaction. Alternatively, in the case where an adverse reaction is determined to have been produced by the drug using any one of the paired T-test and the McNemar test, the drug may be determined to have produced an adverse reaction.
- [89] Second embodiment: system and method for detecting an adverse reaction to an intervention
- [90] The system for detecting an adverse reaction to an intervention according to the second embodiment of the present invention will be described below with reference to FIG. 1.
- [91] The system for detecting an adverse reaction to an intervention according to the second embodiment of the present invention includes an Adverse Intervention Reaction (AIR) signal database, an AIR management unit, a suspect intervention selector, and an AIR detection algorithm, instead of the ADR signal database 110, ADR management unit 100, suspect drug selector 200 and ADR detection algorithm 400 of the system for detecting an adverse reaction to a drug according to the first embodiment of the present invention shown in FIG. 1. Accordingly, only portions different from those of the first embodiment will now be described.
- [92] The system for detecting an adverse reaction to an intervention according to the

second embodiment of the present invention employs the EMR database 10 which was constructed previously. The EMR database 10 may be a database established using any conventional method. It is preferred that the EMR database 10 include intervention information and various pieces of test information about patients.

- [93] Furthermore, a test for an adverse reaction to an intervention may be performed in the EMR database 10. If data is copied to an additional data warehouse (not shown) and a test for an adverse reaction to an intervention is performed using the data warehouse, a load is not exerted on the existing EMR database 10. The data warehouse may be of any type which can store and load data. In an embodiment, it may be a server.
- [94] A user may select a test from which an adverse reaction to an intervention can be detected, and control test numerical values (i.e., criteria) using the AIR management unit 100. Here, the normal and abnormal numerical values of test results are converted into signals and stored in the AIR signal database 110. The AIR management unit 100 may provide a user with all the test lists, test names, and test numerical values. A user may modify, delete, and insert the signals using an additional input unit.
- [95] A user may select an intervention to be monitored through the suspect intervention selector 200. The suspect intervention selector 200 may provide the entire intervention list to a user and provide a separate search function to the user.
- [96] A user may select a specific patient group on the basis of data of the EMR database 10 through the search space reducer 300. For example, a user may select a group of patients having a specific sex, age and intervention period from among patients on whom an intervention was performed.
- [97] The AIR detection algorithm 400 functions to search test results before and after intervention and to set data for the test results. The AIR detection algorithm 400 may include a first intervention time check unit, a test check unit, and a representative value selection unit.
- [98] The first intervention time check unit checks a date on which an intervention was first performed on a patient (hereinafter referred to as a 'first intervention time'). Whether there has been an adverse reaction due to the corresponding intervention can be checked by performing tests before and after the first intervention time.
- [99] Accordingly, the test check unit extracts a target patient on which a test was performed by checking whether the corresponding test was performed before and after the intervention time. In this process, the target patient can be extracted from a group of patients previously selected by the search space reducer 300.
- [100] The representative value selection unit extracts test results before and after the intervention, time and selects representative values from among the test results.
- [101] The statistical analysis system 500 may perform statistical verification on the

comparison of the averages before and after intervention (paired T-test) or the comparison of abnormal appearance frequencies (McNemar test) using data set by the ADR detection algorithm 400, while operating in conjunction with a statistical packet. Statistical verification of any method, other than the paired T-test and the McNemar test, may also be performed.

- [102] In an embodiment, an adverse reaction to an intervention can be checked by performing a paired T-test for comparing the total average of representative values before the intervention and the total average of representative values after the intervention. For example, in the case of a WBC test indicating a leukocyte count, if the WBC has a low numerical value, it may be said to correspond to an adverse reaction. If, as a result of the paired T-test, the numerical value of the WBC is statistically decreased to some extent after the intervention was performed, an adverse reaction is determined to have been produced by the intervention.
- [103] In another embodiment, whether a patient experiences an adverse reaction to an intervention may be checked by comparing a representative value before the intervention and a representative value after the intervention for each patient. Thereafter, '0' may be coded for a normal state and '1' may be coded for an adverse reaction. Whether the intervention has produced an adverse reaction may be finally determined by performing a McNemar test for the numerical values.
- [104] The report system 600 may store and output statistical analysis results, obtained by the statistical analysis system 500, and analysis results, such as the number of target analysis patients.
- [105] The method of detecting an adverse reaction to an intervention according to the second embodiment of the present invention will now be described below with reference to FIGS. 1, 3 and 4. The drug test results A1 to A18 obtained by the system for detecting an adverse reaction to a drug according to the first embodiment of the present invention shown in FIG. 3 are replaced with intervention test results B1 to B18 obtained by the system for detecting an adverse reaction to an intervention according to the second embodiment of the present invention. Accordingly, only portions different from those of the first embodiment will now be described. It is to be noted that FIG. 4 shows the case where a paired T-test and a McNemar test are performed at the same time.
- [106] A user determines an intervention for which an adverse reaction is to be checked, a target patient group, and a test. The intervention for which an adverse reaction is to be checked may be determined by the suspect intervention selector 200. The target patient group may be determined by the search space reducer 300 on the basis of various parameters. The test may be determined by the AIR management unit 100.
- [107] Thereafter, the system extracts only patients on whom the corresponding intervention

was performed from the EMR database 10 at step S120. In the process of extracting the patients to whom the intervention was performed, the system checks the time when the intervention was first performed (i.e., a first intervention time) for each patient at step S220.

[108] In addition to the first intervention time, an intervention period and an intervention end time may be required depending on the type of test or the type of intervention. In this case, the system may check all the times.

[109] Referring to FIG. 3, t0 indicates the EMR start time of a patient, and t1 indicates the EMR end time of the patient. Here, ti is the first intervention time, and te is the intervention end time. In general, the first intervention time ti is used, but the intervention end time te may be used depending on circumstances. The case where the first intervention time ti is used will now be described as an example.

[110] Thereafter, at step S320, patients on whom the determined test was performed before and after the first intervention time ti are extracted from the patients extracted at step S120.

[111] A representative value PreLab before the intervention and a representative value PostLab after the intervention are determined at step S420 by checking the results B1 to B18 of the test performed on the patients extracted at step S320. Which values will become the representative values are quite different depending on the corresponding test.

[112] For example, in the case where a low numerical value corresponds to an adverse reaction as in the case of WBC, a minimum value B8 from among the test results B1 to B9 before the intervention may be determined to be the representative value PreLab before the intervention, and a minimum value B16 from among the test results B10 to B18 after the intervention may be determined to be the representative value PostLab after the intervention.

[113] In contrast, in the case where a high numerical value corresponds to an adverse reaction as in a Creatinine numerical value Cr indicative of a renal function, a maximum value B7 from among the test results B1 to B9 before the intervention may be determined to be the representative value PreLab before the intervention, and a maximum value B17 from among the test results B10 to B18 after the intervention may be determined to be the representative value PostLab after the intervention.

[114] In another embodiment, in the case where some or all of test results are not numerical values, the test results need to be converted into numerical values. For example, in the case of urine protein, test results may be recorded in the form of Neg, Trace, 1+, 2+, and 3+. Neg, Trace, 1+, 2+, and 3+ are converted into numerical values 0, 0, 1, 2, and 3, respectively, and then a representative value PreLab before the intervention and a representative value PostLab after the intervention are determined.

- [115] Whether an adverse reaction has been produced by the intervention is determined by performing statistical verification on the representative value PreLab before the intervention and the representative value PostLab after the intervention at step S520.
- [116] In an embodiment, in accordance with the paired T-test, the total averages of the representative value PreLab before the intervention and the representative value PostLab after the intervention of the patients are compared. If, as a result of the comparison, the representative value PostLab after the intervention has changed and corresponds to predetermined adverse reaction criteria, the corresponding intervention is determined to have produced an adverse reaction.
- [117] In another embodiment, in accordance with the McNemar test, whether a patient experiences an adverse reaction to an intervention may be checked by comparing a representative value PreLab before the intervention and a representative value PostLab after the intervention for each patient. Thereafter, '0' and '1' may be coded depending on whether there has been an adverse reaction at step S620. Whether the intervention has produced an adverse reaction may be finally determined at step S820 by performing statistical analysis, such as frequency analysis, on the values at step S720.
- [118] Here, according to the user settings, in the case where an adverse reaction is determined to have been produced by the intervention using both the paired T-test and the McNemar test, the intervention may be determined to have produced an adverse reaction. Alternatively, in the case where an adverse reaction is determined to have been produced by the intervention using any one of the paired T-test and the McNemar test, the intervention may be determined to have produced an adverse reaction.
- [119] Third embodiment: system and method for detecting an adverse reaction to a drug using ECG data
- [120] The system for detecting an adverse reaction to a drug using ECG data according to the third embodiment of the present invention will now be described with reference to FIG. 1. Although the system for detecting an adverse reaction to a drug will be described as an example below with reference to the drawings, the same algorithm may also be applied to the detection of an adverse reaction to an intervention.
- [121] The system for detecting an adverse reaction to a drug using ECG data according to the third embodiment of the present invention has similar construction and functionality as the system for detecting an adverse reaction to a drug according to the first embodiment of the present invention. Accordingly, descriptions of portions identical to those of the first embodiment will be omitted here.
- [122] In the third embodiment of the present invention, the EMR database 10 may include drug prescription information and ECG test information about patients. A user may select ECG test results from which an adverse reaction to a drug can be detected and control resulting numerical values (i.e., criteria) using the ADR management unit 100.

- [123] Here, the normal and abnormal numerical values of ECG test results are converted into signals and stored in the ADR signal database 110.
- [124] Furthermore, the ADR management unit 100 may provide a user with the ECG test result list and all the ECG test numerical values. The ADR detection algorithm 400 function to search ECG test results before and after the administration of the drug and to set data for the ECG test results. The ADR detection algorithm 400 may include a first time check unit, an ECG test check unit, and a representative value selection unit.
- [125] The first time check unit checks a date on which drug was first administered to a patient (hereinafter referred to as a 'first time'). Whether an adverse reaction has been produced by the drug can be checked by performing ECG tests before and after the checked first time.
- [126] Accordingly, the ECG test check unit checks whether ECG tests have been performed before and after the drug administration time, and extracts target patients on whom the ECG test was been performed. In this process, target patients may be extracted from a group of patients previously selected by the search space reducer 300.
- [127] The representative value selection unit extracts ECG test results before and after the drug administration time, and selects representative values from among the extracted ECG test results.
- [128] An example will now be described with reference to FIG. 5. FIG. 5 shows common ECG test results. A QT interval, a PR interval, a PR segment, an ST segment, and a QRX complex may be used as test results.
- [129] In an embodiment, the QT interval is used as a test result. That is, the total averages of a representative value before the administration of drug PreQT of the QT interval and a representative value PostQT after the administration of the drug of the QT interval are compared with each other. If, as a result of the comparison, the representative value PostQT after the administration of the drug of the QT interval is higher than a reference numerical value, the drug may be determined to have produced an adverse reaction.
- [130] In another embodiment, whether each of the patients experiences an adverse reaction is determined by comparing a representative value before the administration of drug and a representative value after the administration of the drug. Thereafter, '0' may be coded for a normal state and '1' may be coded for an adverse reaction. Whether the drug has produced an adverse reaction is determined by performing a McNemar test for the numerical values.
- [131] The report system 600 may store and output statistical analysis results, obtained by the statistical analysis system 500, and analysis results, such as the number of target analysis patients.
- [132] The method of detecting an adverse reaction to a drug using ECG data according to

the third embodiment of the present invention will now be described with reference to FIGS. 1, 3 and 6. Drug test results A1 to A18 obtained by the system for detecting an adverse reaction to a drug according to the first embodiment of the present invention shown in FIG. 3 are replaced with ECG test results C1 to C18 obtained by the system for detecting an adverse reaction to a drug using ECG data according to the third embodiment of the present invention, and only portions different from those of the first embodiment will now be described below. It is to be noted that FIG. 6 shows the case where a paired T-test and a McNemar test are performed at the same time.

[133] A user determines a drug for which an adverse reaction is to be checked and a target patient group. The drug for which an adverse reaction is to be checked may be determined by the suspect drug selector 200. The target patient group may be determined by the search space reducer 300 on the basis of various parameters.

[134] Thereafter, the system extracts only patients to whom the drug was administered from the EMR database 10 at step S130. In the process of extracting the patients to whom the drug was administered, the system checks the time when the drug was first administered (i.e., a first time) for each patient at step S230.

[135] In addition to the first time, a drug administration period and a drug administration end time may be required depending on the type of ECG test results or the type of drug. In this case, the system may check all the times.

[136] Referring to FIG. 3, t_0 indicates the EMR start time of a patient, and t_1 indicates the EMR end time of the patient. Here, t_i is the first time, and t_e is the drug administration end time. In general, the first time t_i is used, but the drug administration end time t_e may be used depending on circumstances. The case where the first time t_i is used will now be described as an example.

[137] At step S330, patients on whom a predetermined ECG test was performed before and after the first time t_i are extracted from the patients extracted at step S130.

[138] A representative value PreECG before the administration of the drug and a representative value PostECG after the administration of the drug of the ECG test results are determined at step S430 by checking the results C1 to C18 of the ECG test performed on the patients extracted at step S330. FIG. 3 shows the case where the QT interval is used as a test result and shows the process of determining a representative value PreQT before the administration of the drug of the QT interval and a representative value PostQT after the administration of the drug of the QT interval.

[139] Which values will become the representative values are quite different depending on the corresponding test.

[140] For example, in the case where a high numerical value corresponds to an adverse reaction as in the QT interval, a maximum value C7 from among the ECG test results C1 to C9 before the administration of the drug may be determined to be the repre-

sentative value PreECG before the administration of the drug, and a maximum value C17 from among the ECG test results C10 to C18 after the administration of the drug may be determined to be the representative value PostECG after the administration of the drug.

- [141] In contrast, in the case where a low numerical value corresponds to an adverse reaction, a minimum value C8 from among the ECG test results C1 to C9 before the administration of the drug may be determined to be the representative value PreECG before the administration of the drug, and a minimum value C16 from among the ECG test results C10 to C18 after the administration of the drug may be determined to be the representative value PostECG after the administration of the drug.
- [142] Whether there has been an adverse reaction due to the drug is determined by statistically verifying the representative value PreECG before the administration of the drug and the representative value PostECG after the administration of the drug at step S530.
- [143] In an embodiment, in accordance with the paired T-test, the total averages of the representative value PreECG before the administration of the drug and the representative value PostECG after the administration of the drug of the patients are compared. If, as a result of the comparison, the representative value PostECG after the administration of the drug has changed and corresponds to predetermined adverse reaction criteria, the drug is determined to have produced an adverse reaction.
- [144] In another embodiment, in accordance with the McNemar test, whether the patients experience an adverse reaction is checked by comparing the representative value before the administration of drug PreECG and the representative value PostECG after the administration of the drug of each of the patients. '0' and '1' are coded depending on whether there has been an adverse reaction at step S630. Thereafter, whether the drug has produced an adverse reaction is finally determined at step S830 by performing statistical analysis, such as frequency analysis at step S730.
- [145] Here, according to the user settings, in the case where an adverse reaction is determined to have been produced by the drugs using both the paired T-test and the McNemar test, the drug may be determined to have produced an adverse reaction. Alternatively, in the case where an adverse reaction is determined to have been produced by the drug using any one of the paired T-test and the McNemar test, the drug may be determined to have produced an adverse reaction.
- [146] Meanwhile, a system and method for detecting an adverse reaction to an intervention using ECG data may be implemented using the same algorithm as the system and method for detecting an adverse reaction to a drug using ECG data. That is, whether the intervention has produced an adverse reaction may be checked, as shown in descriptions in which the administration of a drug has been replaced with the practice of

intervention in the descriptions of the above embodiments.

[147] More particularly, an adverse reaction to an intervention may be determined by checking a first time t_i when the intervention was first performed, checking a representative value PreECG before the intervention' and a representative value PostECG after the intervention', and performing statistical verification, such as that described above. In this case, an AIR management unit and an AIR detection algorithm may be used respectively instead of the ADR management unit 100 and the ADR detection algorithm 400 used in the system.

[148] Although the preferred embodiments of the present invention have been disclosed for illustrative purposes, those skilled in the art will appreciate that various modifications, additions and substitutions are possible, without departing from the scope and spirit of the invention as disclosed in the accompanying claims.

Claims

[Claim 1]

A method of detecting an adverse reaction to a drug using an Electronic Medical Record (EMR), the method comprising the steps of:

- (a) determining a drug for which an adverse reaction is to be checked and a test for detecting the adverse reaction;
- (b) selecting patients to whom the drug was administered from an EMR database;
- (c) checking a first administration time t_i when the drug was first administered to the selected patients;
- (d) extracting patients on whom the test was performed before and after the first administration time t_i from the selected patients;
- (e) determining a representative value PreLab before the administration of the drug and a representative value PostLab after the administration of the drug, from among results of the test for the extracted patients based on the first administration time t_i ; and
- (f) determining whether the drug have produced the adverse reaction by performing statistical verification on the representative value PreLab before the administration of the drug and the representative value PostLab after the administration of the drug.

[Claim 2]

The method according to claim 1, wherein the step (e) comprises the step of, if the test determines that there has been an adverse reaction if the results of the test are lower than a specific reference numerical value, determining a minimum value, selected from among the results of the test before the drug was administered to the extracted patients, to be the representative value PreLab before the administration of the drug, and determining a minimum value, selected from among the results of the test after the drug was administered to the extracted patients, to be the representative value PostLab after the administration of the drug, based on the first administration time.

[Claim 3]

The method according to claim 1, wherein the step (e) comprises the step of, if the test determines that there has been an adverse reaction if the results of the test are higher than a specific reference numerical value, determining a maximum value, selected from among the results of the test before the drug was administered to the extracted patients, to be the representative value PreLab before the administration of the drug, and determining a maximum value, selected from among the results of the test after the drug was administered to the extracted

patients, to be the representative value PostLab after the administration of the drug, based on the first administration time.

[Claim 4]

The method according to claim 1, wherein the step (e) comprises the steps of:

(e1) converting the results of the test into numerical values; and
(e2) determining the representative value PreLab before the administration of the drug and the representative value PostLab after the administration of the drug, from among the numerical values of the test for the extracted patients, based on the first administration time t_i .

[Claim 5]

The method according to any one of claims 1 to 4, wherein at the step (f), the statistical verification comprises one or more selected from the group consisting of a paired T-test and a McNemar test.

[Claim 6]

The method according to any one of claims 1 to 4, wherein the step (f) comprises the steps of:

(f1) determining whether each of the patients experiences an adverse reaction using the representative value PreLab before the administration of the drug and the representative value PostLab after the administration of the drug;
(f2) coding different numerical values for a normal state and for the adverse reaction based on results of the determination; and
(f3) determining whether the drug has produced the adverse reaction by comparing frequencies of the coded adverse reaction.

[Claim 7]

The method according to any one of claims 1 to 4, wherein:
the step (a) comprises the step of selecting a patient group which is an object of whether there has been an adverse reaction; and
the step (b) comprises selecting the patients to whom the drug was administered from the patient group selected from the EMR database.

[Claim 8]

The method according to any one of claims 1 to 4, wherein the step (b) comprises the steps of:

copying data of the EMR database to a data warehouse; and
selecting the patients to whom the drug was administered from the data copied to the data warehouse.

[Claim 9]

A method of detecting an adverse reaction to an intervention using an EMR, the method comprising the steps of:

(a) determining intervention for which an adverse reaction is to be checked and a test for detecting the adverse reaction;
(b) selecting patients on which the intervention was performed from an EMR database;

- (c) checking a first intervention time t_i when the intervention was first performed on the selected patients;
- (d) extracting patients on whom the test was performed before and after the first intervention time t_i from the selected patients;
- (e) determining a representative value PreLab before the intervention and a representative value PostLab after the intervention, from among results of the test for the extracted patients, based on the first intervention time t_i ; and
- (f) determining whether the intervention has produced the adverse reaction by performing statistical verification on the representative value PreLab before the intervention and the representative value PostLab after the intervention.

[Claim 10]

The method according to claim 9, wherein the step (e) comprises the step of, if the test determined that there has been an adverse reaction if the results of the test are lower than a specific reference numerical value, determining a minimum value, selected from among the results of the test before the intervention was performed on the extracted patients, to be the representative value PreLab before the intervention, and determining a minimum value, selected from among the results of the test after the intervention was performed on the extracted patients, to be the representative value PostLab after the intervention, based on the first intervention time.

[Claim 11]

The method according to claim 9, wherein the step (e) comprises the step of, if the test determines that there has been an adverse reaction if the results of the test are higher than a specific reference numerical value, determining a maximum value, selected from among the results of the test before the intervention was performed on the extracted patients, to be the representative value PreLab before the intervention, and determining a maximum value, selected from among the results of the test after the intervention was performed on the extracted patients, to be the representative value PostLab after the intervention, based on the first intervention time.

[Claim 12]

A method of detecting an adverse reaction to a drug using EMR and electrocardiogram (ECG) data, the method comprising the steps of:

- (a) determining drug for which an adverse reaction is to be checked;
- (b) selecting patients to whom the drug was administered from an EMR database;
- (c) checking a first time t_i when the drug was first administered to the

selected patients;

(d) extracting patients on whom an ECG test was performed before and after the first time t_i from the selected patients;

(e) determining a representative value PreECG before the administration of the drug and a representative value PostECG after the administration of the drug, from among results of the ECG test for the extracted patients, based on the first time t_i ; and

(f) determining whether the drug have produced the adverse reaction by performing statistical verification on the representative value PreECG before the administration of the drug and the representative value PostECG after the administration of the drug.

[Claim 13]

The method according to claim 12, wherein the step (e) comprises the step of, if the ECG test determines that there has been an adverse reaction if the results of the test are lower than a specific reference numerical value, determining a minimum value, selected from among the results of the ECG test before the drug was administered to the extracted patients, to be the representative value PreECG before the administration of the drug, and determining a minimum value, selected from among the results of the ECG test after the drug was administered to the extracted patients, to be the representative value PostECG after the administration of the drug, based on the first time.

[Claim 14]

The method according to claim 12, wherein the step (e) comprises the step of, if the ECG test determined that there has been an adverse reaction if the results of the test are higher than a specific reference numerical value, determining a maximum value, selected from among the results of the ECG test before the drug was administered to the extracted patients, to be the representative value PreECG before the administration of the drug, and determining a maximum value, selected from among the results of the ECG test after the drug was administered to the extracted patients, to be the representative value PostECG after the administration of the drug, based on the first time.

[Claim 15]

A method of detecting an adverse reaction to an intervention using EMR and ECG data, the method comprising the steps of:

(a) determining an intervention for which an adverse reaction is to be checked;

(b) selecting patients to whom the intervention has been performed from an EMR database;

(c) checking a first time t_i when the intervention was first performed on

the selected patients;

(d) extracting patients on whom an ECG test was performed before and after the first time t_i from the selected patients;

(e) determining a representative value PreECG' before the intervention and a representative value PostECG' after the intervention, from among results of the ECG test for the extracted patients, based on the first time t_i ; and

(f) determining whether the intervention has the adverse reaction by performing statistical verification on the representative value PreECG' before the intervention and the representative value PostECG' after the intervention.

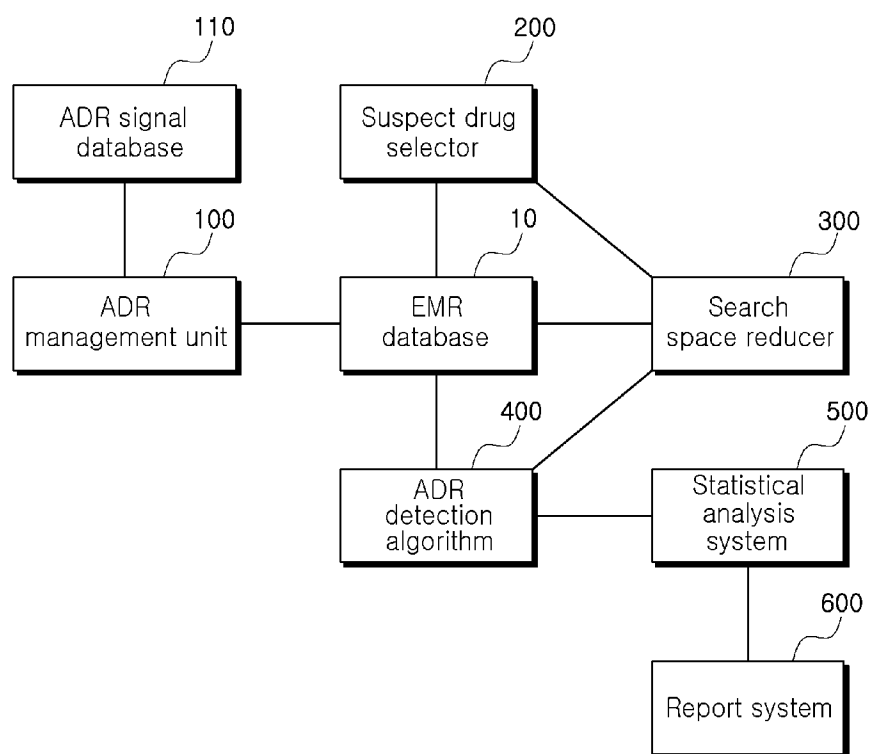
[Claim 16]

The method according to claim 15, wherein the step (e) comprises the step of, if the ECG test determines that there has been an adverse reaction if the results of the test are lower than a specific reference numerical value, determining a minimum value, selected from among the results of the ECG test before the intervention was performed on the extracted patients, to be the representative value PreECG' before the intervention, and determining a minimum value, selected from among the results of the ECG test after the intervention was performed on the extracted patients, to be the representative value PostECG' after the intervention, based on the first time.

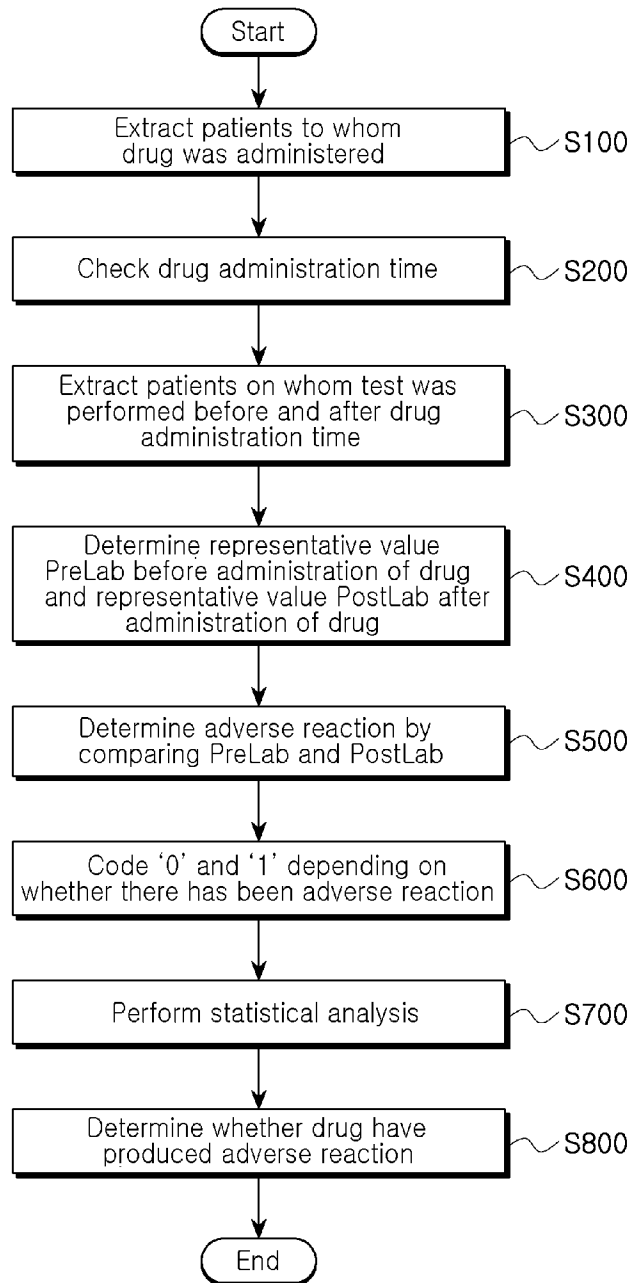
[Claim 17]

The method according to claim 15, wherein the step (e) comprises the step of, if the ECG test determines that there has been an adverse reaction if the results of the test are higher than a specific reference numerical value, determining a maximum value, selected from among the results of the ECG test before the intervention was performed on the extracted patients, to be the representative value PreECG' before the intervention, and determining a maximum value, selected from among the results of the ECG test after the intervention was performed on the extracted patients, to be the representative value PostECG' after the intervention, based on the first time.

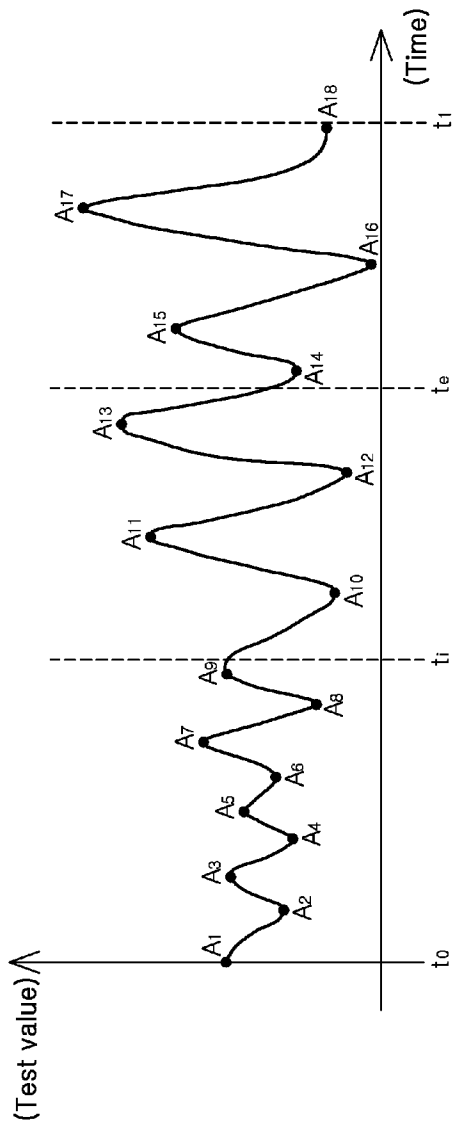
[Fig. 1]



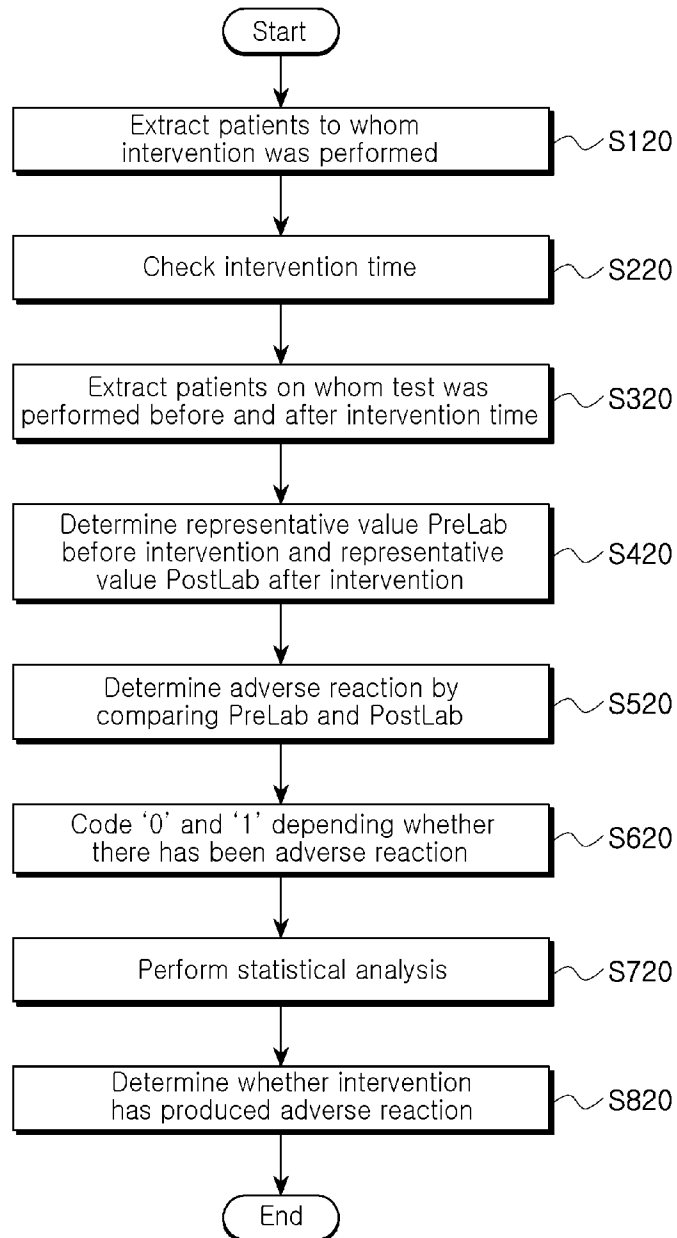
[Fig. 2]



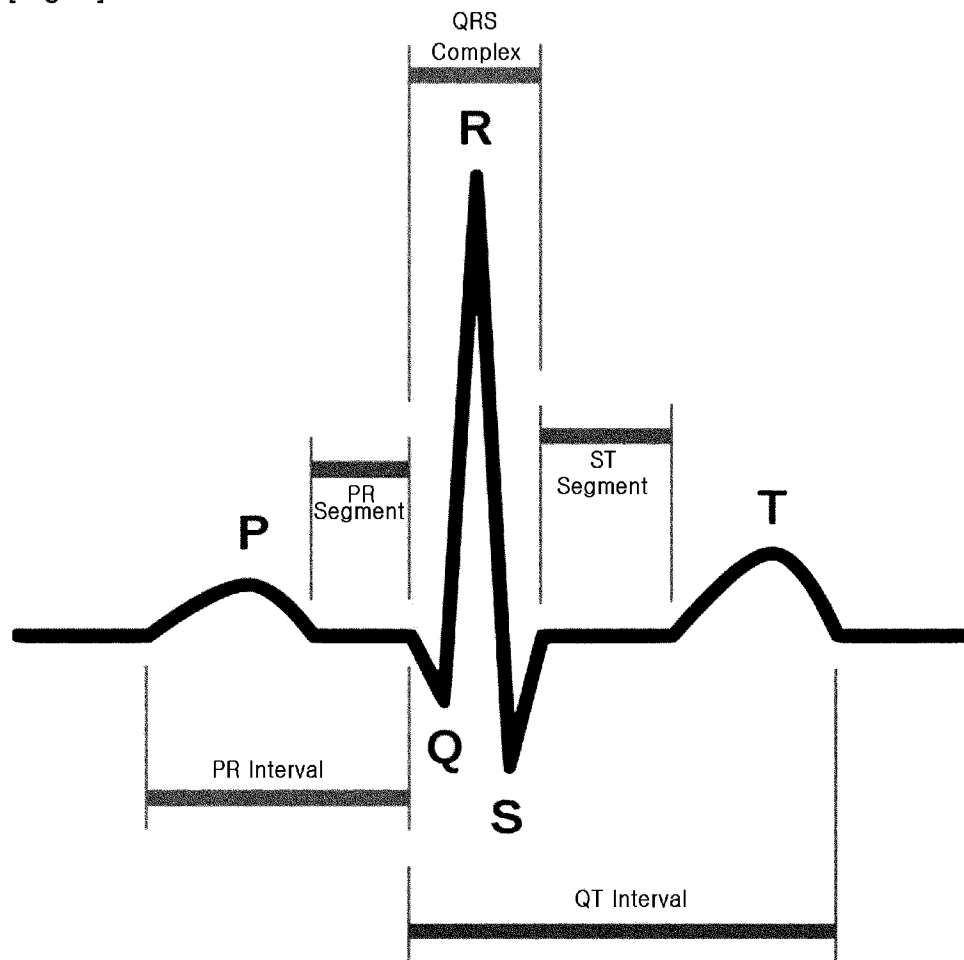
[Fig. 3]



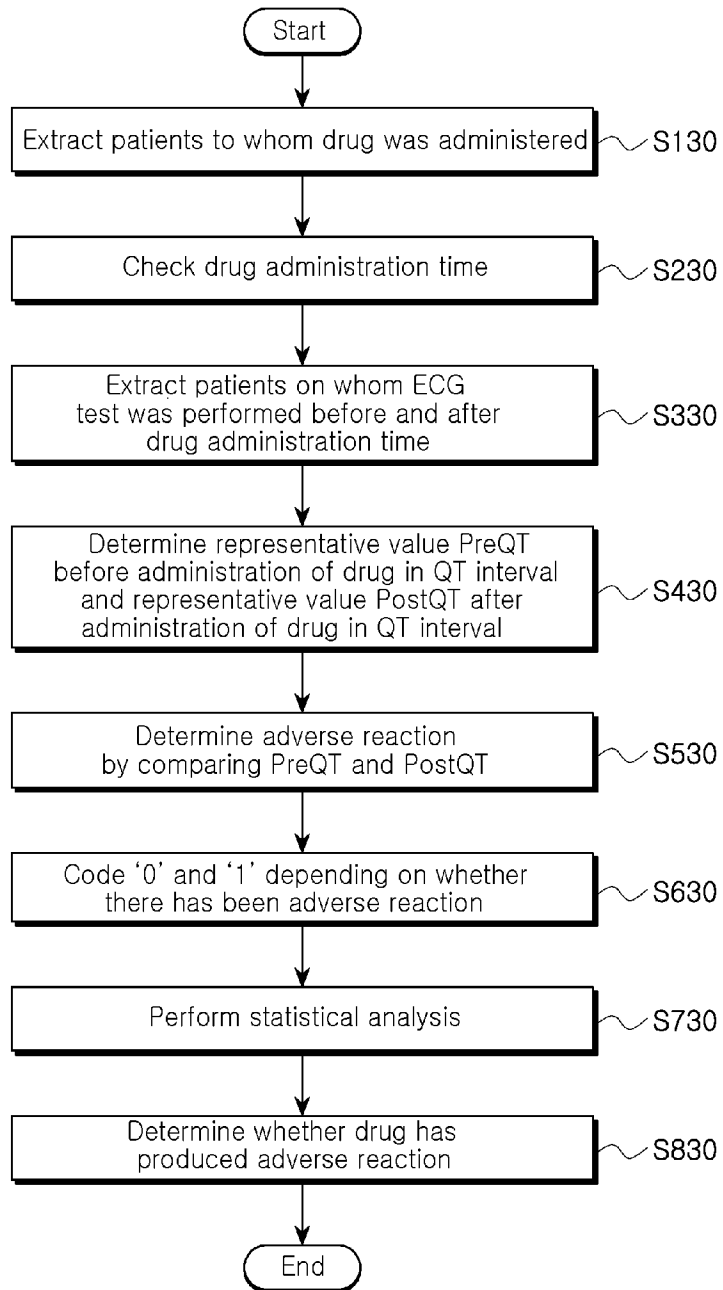
[Fig. 4]



[Fig. 5]



[Fig. 6]



INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2011/001353**A. CLASSIFICATION OF SUBJECT MATTER****G06Q 50/00(2006.01)i, A61B 5/0402(2006.01)i**

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)

G06Q 50/00; G06F 17/30; G06Q 50/00F0; A61B 5/00

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: drug, adverse reaction, test, EMR

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AJOU UNIVERSITY INDUSTRY-ACADEMIC COOPERATION FOUNDATION. A study of adverse drug reaction & drug-drug interaction. Korea Food & Drug Administration. January 2008 See page 14, line 1 - page 52, line 15.	1-17
A	KR 10-2009-0042674 A (KOREA FOOD & DRUG ADMINISTRATION) 30 April 2009 See page 4, line 2 - page 5, line 5 and claims 2, 3.	1-17
A	JP 2009-011829 A (GENERAL ELECTRIC CO.) 22 January 2009 See See page 5, paragraph [0026] - page 6, paragraph [0030].	1-17
A	KR 10-2009-0071564 A (LEAD HORSE TECHNOLOGIES, INC.) 01 July 2009 See page 4, line 43 - page 9, line 9.	1-17

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

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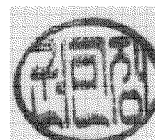
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

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