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(54) 발명의 명칭 MHC-1-병증 위험 일배체형을 치료하는 물질 및 방법

(57) 요약

본 발명은 부분적으로 HLA-A29 또는 HLA-B27 억제성 핵산 분자와 조합된 치료 유효량의 소포체 아미노펩티다제 2(ERAP2) 억제제를 대상체에게 투여함으로써 면역 장애를 갖는 대상체를 치료하는 방법에 관한 것이다.

대표도

두 번째 HLA 대립형질	Upatis (A29 EUR 보유자)				GHS 코호트 #1 (A29 EUR)				GHS 코호트 #2 (A29 EUR)				UKB (A29 EUR)			
	시점 n=286	대상군 n=108	OR (LCI-UCI)	P-값	보유자 n=6014	OR (LCI-UCI)	P-값	보유자 n=2829	OR (LCI-UCI)	P-값	보유자 n=38,543	OR (LCI-UCI)	P-값	보유자 n=38,543	OR (LCI-UCI)	P-값
Refer co-priming	41	4	6.41 (1.58-17.52)	2.20E-03	247	2.83 (1.55-5.70)	1.20E-06	164	2.69 (1.81-4.02)	1.97E-06	2318	2.51 (1.78-3.52)	6.82E-07	2318	2.51 (1.78-3.52)	6.82E-07
A3801	13	1	9.19 (0.76-222.40)	0.12	45	6.31 (2.11-18.26)	6.18E-05	29	6.40 (2.16-19.53)	2.52E-06	396	6.60 (2.19-19.89)	1.20E-05	396	6.60 (2.19-19.89)	1.20E-05
A3301	9	0	Inf (0.77-Inf)	0.07	38	0.40 (1.43-7.27)	0.20E-03	32	2.80 (1.16-6.69)	0.01	285	4.18 (2.10-8.33)	6.33E-04	285	4.18 (2.10-8.33)	6.33E-04
A0301	26	15	0.83 (0.31-1.35)	0.20	592	0.59 (0.38-0.90)	0.01	380	0.63 (0.40-0.97)	0.03	5497	0.50 (0.38-0.66)	0.01	5497	0.50 (0.38-0.66)	0.01
A0101	71	17	1.81 (0.99-3.30)	0.04	862	1.73 (1.26-2.31)	2.67E-04	448	1.74 (1.26-2.33)	3.21E-04	7411	1.39 (1.05-1.83)	0.02	7411	1.39 (1.05-1.83)	0.02
A3201	3	4	0.28 (0.04-1.79)	0.10	192	0.20 (0.04-0.82)	0.01	109	0.27 (0.08-0.89)	0.02	1123	0.20 (0.08-0.48)	0.02	1123	0.20 (0.08-0.48)	0.02
A0201	64	24	1.03 (0.59-1.85)	1.00	1080	0.80 (0.59-1.08)	0.14	798	0.78 (0.57-1.04)	0.09	10680	0.78 (0.56-1.09)	0.05	10680	0.78 (0.56-1.09)	0.05
A2902	19	1	3.79 (0.65-173.22)	0.30	48	2.87 (1.37-6.23)	0.00E-03	32	2.78 (1.16-6.30)	0.02	756	1.87 (0.85-4.08)	0.08	756	1.87 (0.85-4.08)	0.08
A2801	8	3	1.03 (0.24-4.53)	1.00	115	1.00 (0.42-2.07)	1.00	91	0.85 (0.35-1.79)	0.86	834	1.30 (0.55-2.62)	0.41	834	1.30 (0.55-2.62)	0.41
A2501	3	2	0.57 (0.05-6.95)	0.62	101	0.42 (0.08-1.28)	0.16	47	0.62 (0.12-3.04)	0.62	673	0.60 (0.12-2.77)	0.50	673	0.60 (0.12-2.77)	0.50
A2402	23	11	0.79 (0.35-1.86)	0.55	356	0.92 (0.57-1.44)	0.83	249	0.89 (0.55-1.40)	0.74	2801	1.12 (0.69-1.72)	0.57	2801	1.12 (0.69-1.72)	0.57
A3101	9	2	5.79 (0.26-125.95)	0.73	115	1.13 (0.59-2.23)	0.73	75	1.13 (0.51-2.50)	0.87	1615	1.29 (0.55-3.02)	0.59	1615	1.29 (0.55-3.02)	0.59
A1101	14	10	0.52 (0.21-1.34)	0.16	255	0.76 (0.41-1.36)	0.44	177	0.76 (0.40-1.33)	0.44	2278	0.52 (0.44-1.40)	0.61	2278	0.52 (0.44-1.40)	0.61
A2301	6	2	1.16 (0.25-5.93)	1.00	84	0.92 (0.33-2.10)	1.00	61	0.96 (0.34-2.64)	1.00	672	1.21 (0.44-3.28)	0.65	672	1.21 (0.44-3.28)	0.65
A6801	9	6	0.42 (0.14-1.27)	0.09	126	1.01 (0.45-2.01)	0.86	100	0.87 (0.38-1.76)	0.87	1142	1.07 (0.48-2.05)	0.86	1142	1.07 (0.48-2.05)	0.86
A19 대립형질 29,30,31,32,33	44	8	2.07 (0.92-4.64)	0.08	399	1.49 (1.02-2.18)	0.04	269	1.58 (1.07-2.34)	0.02	3739	1.51 (1.04-2.18)	0.03	3739	1.51 (1.04-2.18)	0.03

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명세서

청구범위

청구항 1

면역 장애를 갖는 대상체 치료 방법에서,

상기 방법은 소포체 아미노펩티다제 2(ERAP2) 억제제 및: i) HLA-A29 억제제 및/또는 ii) HLA-B27 억제제를 상기 대상체에게 투여하는 것을 포함하는 대상체 치료 방법.

청구항 2

제1항에 있어서,

상기 면역 장애는 MHC-1-병증인, 방법.

청구항 3

제2항에 있어서,

상기 MHC-1-병증은 BSCR(산탄 맥락망막병증)이고,

상기 방법은 상기 ERAP2 억제제와 상기 HLA-A29 억제제를 상기 대상체에게 투여하는 것을 포함하는, 방법.

청구항 4

제 3항에 있어서,

상기 방법은 상기 대상체로부터 수득한 생물학적 샘플에서 HLA-A29 대립유전자의 존재 또는 부재를 검출하는 것을 더 포함하는, 방법.

청구항 5

제 4항에 있어서,

상기 방법은 상기 대상체가 HLA-A29 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 것을 더 포함하는, 방법.

청구항 6

제3항 내지 제5항 중 어느 한 항에 있어서,

상기 HLA-A29 억제제는 항체를 포함하는, 방법.

청구항 7

제3항 내지 제5항 중 어느 한 항에 있어서,

상기 HLA-A29 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 방법.

청구항 8

제7항에 있어서,

상기 억제성 핵산 분자는 HLA-A29에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 방법.

청구항 9

제8항에 있어서,

상기 안티센스 핵산 분자는 서열번호 3871 내지 4145로 이루어진 군으로부터 선택된 뉴클레오타이드 서열을 포함

하는, 방법.

청구항 10

제8항에 있어서,

상기 siRNA 분자는 서열번호 4146 내지 4755로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 방법.

청구항 11

제2항에 있어서,

상기 MHC-1-병증은 강직성 척추염(AS)이고, 상기 대상체에게 상기 ERAP2 억제제와 상기 HLA-B27 억제제를 투여하는 것을 포함하는, 방법.

청구항 12

제11항에 있어서,

상기 방법은 상기 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 대립유전자의 존재 또는 부재를 검출하는 것을 더 포함하는, 방법.

청구항 13

제12항에 있어서,

상기 방법은 상기 대상체가 HLA-B27 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 것을 더 포함하는, 방법.

청구항 14

제11항 내지 제13항 중 어느 한 항에 있어서,

상기 HLA-B27 억제제는 항체를 포함하는, 방법.

청구항 15

제11항 내지 제13항 중 어느 한 항에 있어서,

상기 HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 방법.

청구항 16

제15항에 있어서,

상기 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 방법.

청구항 17

제16항에 있어서,

상기 안티센스 핵산 분자는 서열번호 2788 내지 3132로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 방법.

청구항 18

제16항에 있어서,

상기 siRNA 분자는 서열번호 3133 내지 3870으로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 방법.

청구항 19

제2항에 있어서,

상기 MHC-1-병증은 건선이고, 상기 대상체는 포도막염 또한 가지고 있고, 상기 대상체에게 상기 ERAP2 억제제와 상기 HLA-B27 억제제를 투여하는 것을 포함하는, 방법.

청구항 20

제19항에 있어서,

상기 방법은 상기 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 대립유전자의 존재 또는 부재를 검출하는 것을 더 포함하는, 방법.

청구항 21

제20항에 있어서,

상기 방법은 상기 대상체가 HLA-B27 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 것을 더 포함하는, 방법.

청구항 22

제19항 내지 제21항 중 어느 한 항에 있어서,

상기 HLA-B27 억제제는 항체를 포함하는, 방법.

청구항 23

제19항 내지 제21항 중 어느 한 항에 있어서,

상기 HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 방법.

청구항 24

제23항에 있어서,

상기 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 방법.

청구항 25

제24항에 있어서,

상기 안티센스 핵산 분자는 서열번호 2788 내지 3132로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 방법.

청구항 26

제24항에 있어서,

상기 siRNA 분자는 서열번호 3133 내지 3870로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 방법.

청구항 27

제2항에 있어서,

상기 MHC-1-병증은 소아 특발성 관절염(JIA)이고, 상기 방법은 상기 대상체에게 상기 ERAP2 억제제와 상기 HLA-B27 억제제를 투여하는 것을 포함하는, 방법.

청구항 28

제27항에 있어서,

상기 방법은 상기 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 대립유전자의 존재 또는 부재를 검출하는 단

계를 더 포함하는, 방법.

청구항 29

제28항에 있어서,

상기 방법은 상기 대상체가 HLA-B27 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 것을 더 포함하는, 방법.

청구항 30

제27항 내지 제29항 중 어느 한 항에 있어서,

상기 HLA-B27 억제제는 항체를 포함하는, 방법.

청구항 31

제27항 내지 제29항 중 어느 한 항에 있어서,

상기 HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 방법.

청구항 32

제31항에 있어서,

상기 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 방법.

청구항 33

제32항에 있어서,

상기 안티센스 핵산 분자는 서열번호 2788 내지 3132로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 방법.

청구항 34

제32항에 있어서,

상기 siRNA 분자는 서열번호 3133 내지 3870로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 방법.

청구항 35

제1항 내지 제34항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 방법.

청구항 36

제35항에 있어서,

상기 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 방법.

청구항 37

제36항에 있어서,

상기 안티센스 핵산 분자는 서열번호 1 내지 858로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 방법.

청구항 38

제36항에 있어서,

상기 siRNA 분자는 서열번호 859 내지 2748로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 방법.

청구항 39

제1항 내지 제34항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 항-ERAP2 항체를 포함하는, 방법.

청구항 40

제1항 내지 제34항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 슈도펩티드를 포함하는, 방법.

청구항 41

제 40항에 있어서,

상기 슈도펩티드는 포스피닉 슈도펩티드인, 방법.

청구항 42

제41항에 있어서,

상기 포스피닉 슈도펩티드는 DG002 또는 DG013인, 방법.

청구항 43

제1항 내지 제34항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 소분자를 포함하는, 방법.

청구항 44

MHC-1-병증을 가진 대상체를 치료하는 방법에서,

하기를 포함하는지 여부를 결정하기 위해 상기 대상체의 생물학적 샘플에 대한 검정을 수행하거나 수행했던 단계:

- i) HLA-A29 대립유전자 및/또는 HLA-B27 대립유전자; 및
- ii) 기능적 소포체 아미노펩티다제 2(ERAP2) 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자; 및

상기 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 상기 핵산 분자를 갖고 상기 HLA-A29 대립유전자를 갖는 상기 대상체에게 치료적 유효량의 ERAP2 억제제와 HLA-A29 억제제를 투여하는 단계; 또는

상기 기능적 ERAP2 단백질 또는 상기 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 갖고 상기 HLA-B27 대립유전자를 갖는 상기 대상체에게 치료적 유효량의 ERAP2 억제제와 HLA-B27 억제제를 투여하는 단계;를 포함하며,

- i) 상기 HLA-A29 대립유전자 및/또는 상기 HLA-B27 대립유전자 및 ii) 상기 기능적 ERAP2 단백질 또는 상기 기능적 ERAP2 단백질을 암호화하는 핵산 분자 모두의 존재는 상기 대상체가 ERAP2를 억제함으로써 MHC-1-병증을 치료할 후보임을 나타내는, MHC-1-병증을 가진 대상체를 치료하는 방법.

청구항 45

제44항에 있어서,

상기 MHC-1-병증은 BSCR(산탄 맥락망막병증)이고, 상기 방법은 상기 ERAP2 억제제와 상기 HLA-A29 억제제를 상기 대상체에게 투여하는 것을 포함하는, 방법.

청구항 46

제45항에 있어서,

상기 방법은 상기 대상체로부터 수득한 생물학적 샘플에서 HLA-A29 대립유전자의 존재 또는 부재를 검출하는 단계를 더 포함하는, 방법.

청구항 47

제46항에 있어서,

상기 방법은 상기 대상체가 HLA-A29 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 단계를 더 포함하는, 방법.

청구항 48

제45항 내지 제47항 중 어느 한 항에 있어서,

상기 HLA-A29 억제제는 항체를 포함하는, 방법.

청구항 49

제45항 내지 제47항 중 어느 한 항에 있어서,

상기 HLA-A29 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 방법.

청구항 50

제49항에 있어서,

상기 억제성 핵산 분자는 HLA-A29에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 방법.

청구항 51

제50항에 있어서,

상기 안티센스 핵산 분자는 서열번호 3871 내지 4145로 이루어진 군으로부터 선택된 뉴클레오타이드 서열을 포함하는, 방법.

청구항 52

제50항에 있어서,

상기 siRNA 분자는 서열번호 4146 내지 4755로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 방법.

청구항 53

제44항에 있어서,

상기 MHC-1-병증은 강직성 척추염(AS)이고, 상기 대상체에게 상기 ERAP2 억제제와 상기 HLA-B27 억제제를 투여하는 것을 포함하는, 방법.

청구항 54

제53항에 있어서,

상기 방법은 상기 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 대립유전자의 존재 또는 부재를 검출하는 것을 더 포함하는, 방법.

청구항 55

제54항에 있어서,

상기 방법은 상기 대상체가 HLA-B27 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 것을 더 포함하는, 방법.

청구항 56

제53항 내지 제55항 중 어느 한 항에 있어서,
상기 HLA-B27 억제제는 항체를 포함하는, 방법.

청구항 57

제53항 내지 제55항 중 어느 한 항에 있어서,
상기 HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 방법.

청구항 58

제57항에 있어서,
상기 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 방법.

청구항 59

제58항에 있어서,
상기 안티센스 핵산 분자는 서열번호 2788 내지 3132로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 방법.

청구항 60

제58항에 있어서,
상기 siRNA 분자는 서열번호 3133 내지 3870로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 방법.

청구항 61

제44항에 있어서,
상기 MHC-1-병증은 건선이고, 상기 대상체는 포도막염 또한 가지고 있고, 상기 방법은 상기 대상체에게 상기 ERAP2 억제제와 상기 HLA-B27 억제제를 투여하는 것을 포함하는, 방법.

청구항 62

제61항에 있어서,
상기 방법은 상기 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 대립유전자의 존재 또는 부재를 검출하는 단계를 더 포함하는, 방법.

청구항 63

제62항에 있어서,
상기 방법은 상기 대상체가 HLA-B27 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 것을 더 포함하는, 방법.

청구항 64

제61항 내지 제63항 중 어느 한 항에 있어서,
상기 HLA-B27 억제제는 항체를 포함하는, 방법.

청구항 65

제61항 내지 제63항 중 어느 한 항에 있어서,

상기 HLA-B27억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 방법.

청구항 66

제65항에 있어서,

상기 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 방법.

청구항 67

제66항에 있어서,

상기 안티센스 핵산 분자는 서열번호 2788 내지 3132로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 방법.

청구항 68

제66항에 있어서,

상기 siRNA 분자는 서열번호 3133 내지 3870으로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 방법.

청구항 69

제44항에 있어서,

상기 MHC-1-병증은 소아 특발성 관절염(JIA)이고, 상기 방법은 상기 대상체에게 상기 ERAP2 억제제와 상기 HLA-B27 억제제를 투여하는 것을 포함하는, 방법.

청구항 70

제69항에 있어서,

상기 방법은 상기 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 대립유전자의 존재 또는 부재를 검출하는 단계를 더 포함하는, 방법.

청구항 71

제70항에 있어서,

상기 방법은 상기 대상체가 HLA-B27 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 것을 더 포함하는, 방법.

청구항 72

제69항 내지 제71항 중 어느 한 항에 있어서,

상기 HLA-B27 억제제는 항체를 포함하는, 방법.

청구항 73

제69항 내지 제71항 중 어느 한 항에 있어서,

상기 HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 방법.

청구항 74

제73항에 있어서,

상기 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 방법.

청구항 75

제74항에 있어서,

상기 안티센스 핵산 분자는 서열번호 2788 내지 3132로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 방법.

청구항 76

제74항에 있어서,

상기 siRNA 분자는 서열번호 3133 내지 3870으로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 방법.

청구항 77

제44항 내지 제76항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 방법.

청구항 78

제77항에 있어서,

상기 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 방법.

청구항 79

제78항에 있어서,

상기 안티센스 핵산 분자는 서열번호 1 내지 858로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 방법.

청구항 80

제78항에 있어서,

상기 siRNA 분자는 서열번호 859 내지 2748로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 방법.

청구항 81

제44항 내지 제76항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 항-ERAP2 항체를 포함하는, 방법.

청구항 82

제44항 내지 제76항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 슈도펩티드를 포함하는, 방법.

청구항 83

제 82항에 있어서,

상기 슈도펩티드는 포스포닉 슈도펩티드인, 방법

청구항 84

제83항에 있어서,

상기 포스포닉 슈도펩티드는 DG002 또는 DG013인, 방법.

청구항 85

제44항 내지 제76항 중 어느 한 항에 있어서,
상기 ERAP2 억제제는 소분자를 포함하는, 방법.

청구항 86

면역 장애 치료에 사용하기 위한 소포체 아미노펩티다제 2(ERAP2) 억제제와 HLA-A29 억제제의 조합.

청구항 87

제86항에 있어서,
상기 면역 장애는 MHC-1-병증인, 조합.

청구항 88

제87항에 있어서,
상기 MHC-1-병증은 산탄 맥락망막병증(BSCR, Birdshot Chorioretinopathy)인, 조합.

청구항 89

제86항 내지 제88항 중 어느 한 항에 있어서,
상기 HLA-A29 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 조합.

청구항 90

제89항에 있어서,
상기 억제성 핵산 분자는 HLA-A29에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 조합.

청구항 91

제90항에 있어서,
상기 안티센스 핵산 분자는 서열번호 3871 내지 4145로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 조합.

청구항 92

제90항에 있어서,
상기 siRNA 분자는 서열번호 4146 내지 4755로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 조합.

청구항 93

면역 장애 치료에 사용하기 위한 소포체 아미노펩티다제 2(ERAP2) 억제제와 HLA-B27 억제제의 조합.

청구항 94

제93항에 있어서,
상기 면역 장애는 MHC-1-병증인, 조합.

청구항 95

제 94항에 있어서,
상기 MHC-1-병증은 강직성 척추염(AS)인, 조합.

청구항 96

제93항 내지 제95항 중 어느 한 항에 있어서,
상기 HLA-B27 억제제는 항체를 포함하는, 조합.

청구항 97

제93항 내지 제95항 중 어느 한 항에 있어서,
상기 HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 조합.

청구항 98

제97항에 있어서,
상기 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 조합.

청구항 99

제98항에 있어서,
상기 안티센스 핵산 분자는 서열번호 2788 내지 3132로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 조합.

청구항 100

제98항에 있어서,
상기 siRNA 분자는 서열번호 3133 내지 3870으로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 조합.

청구항 101

제94항에 있어서,
상기 MHC-1-병증은 건선이고, 상기 대상체는 포도막염 또한 가지고 있고, 상기 방법은 상기 대상체에게 상기 ERAP2 억제제와 상기 HLA-B27 억제제를 투여하는 것을 포함하는, 방법.

청구항 102

제93항, 제94항 및 제101항 중 어느 한 항에 있어서,
상기 HLA-B27 억제제는 항체를 포함하는, 조합.

청구항 103

제93항, 제94항 및 제101항 중 어느 한 항에 있어서,
상기 HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 조합.

청구항 104

제103항에 있어서,
상기 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 조합.

청구항 105

제104항에 있어서,
상기 안티센스 핵산 분자는 서열번호 2788 내지 3132로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함

하는, 조합.

청구항 106

제104항에 있어서,

상기 siRNA 분자는 서열번호 3133 내지 3870으로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 조합.

청구항 107

제94항에 있어서,

상기 MHC-1-병증은 소아 특발성 관절염(JIA)이고, 상기 방법은 상기 대상체에게 상기 ERAP2 억제제와 상기 HLA-B27 억제제를 투여하는 것을 포함하는, 조합.

청구항 108

제93항, 제94항 및 제107항 중 어느 한 항에 있어서,

상기 HLA-B27 억제제는 항체를 포함하는, 조합.

청구항 109

제93항, 제94항 및 제107항 중 어느 한 항에 있어서,

상기 HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 조합.

청구항 110

제109항에 있어서,

상기 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 조합.

청구항 111

제110항에 있어서,

상기 안티센스 핵산 분자는 서열번호 2788 내지 3132로 이루어진 군으로부터 선택된 뉴클레오티드 서열을 포함하는, 조합.

청구항 112

제110항에 있어서,

상기 siRNA 분자는 서열번호 3133 내지 3870으로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 조합.

청구항 113

제86항 내지 제112항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함하는, 조합.

청구항 114

제113항에 있어서,

상기 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA를 포함하는, 조합.

청구항 115

제114항에 있어서,

상기 안티센스 핵산 분자는 서열번호 1 내지 858로 이루어진 군으로부터 선택된 뉴클레오타이드 서열을 포함하는, 조합.

청구항 116

제114항에 있어서,

상기 siRNA 분자는 서열번호 859 내지 2748로 이루어진 군으로부터 선택된 센스 가닥 및 상응하는 안티센스 가닥을 포함하는, 조합.

청구항 117

제86항 내지 제 112항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 항-ERAP2 항체를 포함하는, 조합.

청구항 118

제86항 내지 제112항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 슈도펩티드를 포함하는, 조합.

청구항 119

제118항에 있어서,

상기 슈도펩티드는 포스포닉 슈도펩티드인, 조합.

청구항 120

제119항에 있어서,

상기 포스포닉 슈도펩티드는 DG002 또는 DG013인, 조합.

청구항 121

제86항 내지 제112항 중 어느 한 항에 있어서,

상기 ERAP2 억제제는 소분자를 포함하는, 조합.

발명의 설명

기술 분야

[0001] 본 개시내용은 부분적으로 HLA-A29 또는 HLA-B27 억제성 핵산 분자와 조합된 치료 유효량의 소포체 아미노펩티다제 2(ERAP2) 억제제를 대상체에게 투여함으로써 면역 장애를 갖는 대상체를 치료하는 방법에 관한 것이다.

[0002] 서열 목록에 대한 참조

[0003] 본 출원은 2022년 4월 6일에 생성된 1,027 킬로바이트 크기의 18923810702SEQ라는 이름의 텍스트 파일로 전자적으로 제출된 서열 목록을 포함한다. 서열 목록은 참조로 본원에 편입된다.

배경 기술

[0004] 인간의 세포 면역 반응은 적어도 부분적으로는 8-10개 아미노산 길이의 작은 펩티드의 제시에 의존하며, 이는 주요 조직적합성 복합체(MHC)(즉, 클래스 I MHC 분자)의 결합 단백질이다. 이 작은 펩티드는 단백질(외래 항원 및 자기-항원)의 단백질분해효소적 분해에서 유래된다. 이러한 항원의 한 공급원은 분해 시 MHC 클래스 I 분자(MHCI)와 복합체화된 세포 표면 상에 제시되는 별개의 항원 펩티드를 생성하는 특정 단백질 분자를 발현하는 감염되거나 악성으로 형질전환된 세포에서 나온다. 세포독성 T 세포는 분해된 단백질 항원과 MHC 분자의 이러한

복합체를 인식하고 아포토시스 세포 사멸을 유도할 수 있다. 항원성 펩티드의 비정상적 생성은 면역계 회피 또는 자가면역 반응을 유발할 수 있다.

[0005] 대부분의 항원성 펩티드는 초기에 프로테아좀에 의해 생성되지만, 그 중 다수는 최종 항원성 에피토프보다 크고 N-말단에 하나 이상의 추가 아미노산을 함유한다. 이러한 항원성 펩티드 전구체는 소포체(ER)로 들어가서, 적어도 두 가지 다른 아미노펩티다제인 ERAP1과 ERAP2에 의해 더 분해되어 MHC 클래스 I 분자와 복합체를 형성하기 위한 성숙한 항원성 펩티드를 생성한다. 따라서, ERAP1 및 ERAP2의 활성화는 특정 MHC 분자와 복합체화된 항원 펩티드의 제시에 유익하거나 불리한 방식으로 직접 영향을 미쳐 면역 반응을 변화시킬 수 있다. 따라서, ERAP2 활성화 및 그 치료와 관련된 특정 MHC-1-병증을 갖는 대상체를 확인할 필요성이 계속 존재한다.

[0006] 산탄 맥락망막병증(BSCR, Birdshot Chorioretinopathy)은 유럽계 50세 초과의 개체에게 우세하게 영향을 미치고 면역조절 요법으로 치료되는 드문 자가면역 포도막염이다. 이 질병은 맥락막 및 망막 염증성 병변 및 위축으로 인한 유리체염 및 점막적인 시력 저하를 나타낸다. T 세포는 영향을 받은 BSCR 눈의 유리체뿐만 아니라 망막 및 맥락막 조직에서 확인되었다.

발명의 내용

[0007] 본 개시내용은 대상체에게 ERAP2 억제제 및: i) HLA-A29 억제제 및/또는 HLA-B27 억제제를 투여하는 것을 포함하여, 면역 장애를 갖는 대상체를 치료하는 방법을 제공한다.

[0008] 본 개시내용은 MHC-1-병증을 갖는 대상체를 치료하는 방법을 제공하며, 상기 방법은 대상체가 i) HLA-A29 대립유전자 및/또는 HLA-B27 대립유전자; 및 ii) 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 포함하는지 여부를 결정하기 위해 대상체의 생물학적 샘플에 대한 검정을 수행하거나 수행했던 단계; 및 기능적 ERAP2 단백질 또는 기능적 ERAP2를 암호화하는 핵산 분자를 갖고 HLA-A29 대립유전자를 갖는 대상체에게 치료적 유효량의 ERAP2 억제제와 HLA-A29 억제제를 투여하는 단계; 또는 기능적 ERAP2 단백질 또는 기능적 ERAP2를 암호화하는 핵산 분자를 갖고 HLA-B27 대립유전자를 갖는 대상체에게 치료적 유효량의 ERAP2 억제제와 HLA-B27 억제제를 투여하는 단계를 포함하며; i) HLA-A29 대립유전자 및/또는 HLA-B27 대립유전자, 및 ii) 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자의 모두의 존재는 대상체가 ERAP2를 억제함으로써 MHC-1-병증을 치료하기 위한 후보임을 나타낸다.

[0009] 본 개시내용은 면역 장애의 치료에 사용하기 위한 ERAP2 억제제와 HLA-A29 억제제의 조합물을 제공한다.

[0010] 본 개시내용은 면역 장애의 치료에 사용하기 위한 ERAP2 억제제와 HLA-B27 억제제의 조합물을 제공한다.

도면의 간단한 설명

[0011] 본 특허 또는 출원 파일은 컬러로 나타난 적어도 하나의 도면이 들어 있다. 유색 도면(들)이 있는 이러한 특허 또는 특허 출원 공보의 사본은 요청 및 필요한 수수료의 지불 시에 특허청에 의해 제공될 것이다.

도 1은 UKB 및 GHS EUR A29 보유자와 비교한 프랑스 코호트의 HLA-A 두 번째 대립유전자 빈도 표를 보여준다. 위험을 증가시키는 Aw19 광범위 항원 군에 속하는 대립유전자는 A29, A30, A31 및 A33(적색)이고 A32는 보호(녹색)를 나타낸다. 모든 Aw19 위험 대립유전자를 조합한 피서의 정확한 테스트는 모든 비교에서 가장 강력한 농축을 나타낸다. 3개 이상의 사례 보유자가 있는 대립유전자만 제시된다. UKB에서 A29 대조군과 사례 빈도를 비교할 때 표는 p-값으로 정렬된다.

도 2는 산탄(Birdshot) 사례에서 Aw19 농축을 보여준다. 108개의 UParis 대조군(파란색), GHS 대조군 코호트 #1(n= 4,014, 짙은 녹색), GHS 대조군 코호트 #2(n= 2,829, 밝은 녹색) 및 UKB 대조군(n= 38,543, 노란색)과 비교된 286개의 UParis 사례에서 3개 이상의 사례(>1%, x축)에 존재하는 14개의 HLA-A 대립유전자의 빈도를 BSCR에 대한 승산비(Odds-ratio)와 비교하였다. Aw19 대립유전자는 사례에서 고갈된 A32(녹색 상자)를 제외하고 큰 A29 대조군 코호트로 복제되는 가장 높은 OR(적색 상자)을 보여준다. * p<0.01

도 3은 UKB 및 GHS EUR A29 보유자와 비교한 프랑스 코호트의 HLA-A 두 번째 대립유전자 빈도 표를 보여준다. 위험을 증가시키는 Aw19 광범위 항원 군에 속하는 대립유전자는 A29, A30, A31 및 A33(적색)이고 A32는 보호(녹색)를 나타낸다. 각 분석 세트에 대한 유전자 배열 데이터를 기반으로 계산된 성별 및 6가지 주요 구성 요소에 대한 공변량이 포함된 로지스틱 회귀 테스트. 3개 이상의 사례 보유자가 있는 모든 HLA-A 대립유전자에 대한 결과가 제시된다. 대립유전자는 도 1과 같이 정렬된다. *세 가지 주요 구성 요소.

도 4는 ERAP2 영역에서 상위 SNP의 표를 보여준다. ERAP2에서 변이체는 이전 결과(125개 사례 및 670개 대조군

(Kuiper 2014))와 함께 분석할 때 게놈-전체에서 중요하다. Rs10044354는 네덜란드 및 스페인 코호트의 이전 GWAS에서 ERAP1-ERAP2 유전자좌의 상위 연관이며, rs27432는 현재 프랑스 코호트에서 해당 영역의 상위 연관이다. 두 유전자좌 사이의 LD도 제시된다. *참조 A-대립유전자는 마이너 대립유전자이고, 위험은 G-대립유전자이다.

도 5는 ERAP2 스플라이스 영역 변이체가 BSCR에 대해 보호적임을 보여준다. ERAP2 발현을 방해하는 일반적인 ERAP2 스플라이스 영역 변이체 rs2248374는 현재 BSCR 코호트와 이전 스페인 및 네덜란드 코호트에서 보호적이다.

도 6은 ERAP2 및 Aw19의 2개 카피의 조합된 위험을 보여준다. 286개의 산탄(Birdshot) 사례와 GHS 코호트 #1의 4,014개 대조군을 활용하여 ERAP2 및 Aw19에서 위험 요소를 조합하면서 추가적인 위험을 계산한다. rs10044354 rs10044354-CC 및 Aw19 대립유전자(A29) 1개 카피의 최저 위험 조합에 대한 단일(A29/-) 또는 이중(A29/Aw19) Aw19 카피로 태그된 ERAP2 위험 신호의 추가 유전자형 모델.

도 7은 ERAP2와 Aw19의 조합된 위험도 표를 보여준다. 286개의 산탄(Birdshot) 사례와 GHS 코호트 #1의 4,014개 대조군을 활용하여 ERAP2 및 Aw19에서 위험 요소를 조합하면서 추가적인 위험을 계산한다. rs10044354 및 rs10044354-CC 및 Aw19 대립유전자(A29) 1개 카피의 최저 위험 조합에 대한 단일(A29/-) 또는 이중(A29/Aw19) Aw19 카피로 태그된 ERAP2 위험 신호의 추가 유전자형 모델.

도 8은 위험 Aw19 대립유전자와 A32 사이의 차이를 보여준다. 패널 A) 위험 Aw19 대립유전자(적색)와 보호 A32 대립유전자(녹색) 사이의 서열 차이. A32는 참조 A:01:01 대립유전자와 같이 위치 9에서 F를 나타내지만, 위험 대립유전자는 해당 위치에서 T 또는 S이다. Bw4 에피토프 서열은 위치 79-83 또는 A32에서만 명백하다.

발명을 실시하기 위한 구체적인 내용

- [0012] 본 개시내용의 양태와 관련된 다양한 용어가 명세서 및 청구범위 전반에 걸쳐 사용된다. 이러한 용어는 달리 나타내지 않는 한, 해당 기술분야에서 그 통상적인 의미를 가져야 한다. 다른 구체적으로 정의된 용어는 본원에 제공된 정의와 일치하는 방식으로 해석되어야 한다.
- [0013] 명확히 달리 진술되지 않는 한, 본원에서 제시된 임의의 방법 또는 측면은 이의 단계들이 특정 순서로 실시될 것을 요구하는 것으로 이해되는 것은 아니다. 따라서, 단계들이 특정 순서로 제한되는 방법 청구항이 청구항 또는 상세한 설명에 구체적으로 기재되어 있지 않는 경우, 이는 어떠한 면에서도 순서가 추론되는 것으로 의도되지 않는다. 이것은 단계 또는 작동 흐름의 배열과 관련된 논리 문제, 문법적 구성 또는 구두점으로부터 유래된 일반 의미, 명세서에 기재된 양태의 수 또는 유형을 포함하여 해석을 위한 임의의 가능한 비-표현적 근거를 유지한다.
- [0014] 본원에 사용된 단수 형태 "한", "하나" 및 "상기"는, 문맥상 명확히 달리 기재된 바 없는 경우, 복수형 언급을 포함한다.
- [0015] 본원에 사용된 바와 같이, 용어 "약"은 인용된 수치가 근사치이고 작은 변동이 개시된 구현양태의 실시예 상당한 영향을 미치지 않음을 의미한다. 수치가 사용되는 경우, 문맥이 달리 나타내지 않는 한, 용어 "약"은 수치가 $\pm 10\%$ 만큼 변화할 수 있고 개시된 구현양태의 영역 내에 잔류함을 의미한다.
- [0016] 본원에 사용된 바와 같이, 용어 "포함하는"은 원하는 대로 특정 실시형태에서 "이로 이루어지는" 또는 "본질적으로 이로 이루어지는"으로 대체될 수 있다.
- [0017] 본원에 사용된 용어 "핵산", "핵산 분자", "핵산 서열", "폴리뉴클레오타이드" 또는 "올리고뉴클레오타이드"는 임의의 길이의 뉴클레오타이드의 중합체 형태를 포함할 수 있고, DNA 및/또는 RNA를 포함할 수 있고, 단일 가닥, 이중 가닥 또는 다중 가닥일 수 있다. 핵산의 한 가닥은 또한 이의 보체를 의미한다.
- [0018] 본원에 사용된 바와 같이, 용어 "대상체"는 포유동물을 비롯한 임의의 동물을 포함한다. 포유동물은 농장 동물(예를 들어, 말, 소, 돼지와 같음), 반려 동물(예를 들어, 개, 고양이와 같음), 실험실 동물(예를 들어, 마우스, 래트, 토끼와 같음), 및 비인간 영장류(예를 들어, 유인원 및 원숭이와 같음)를 포함하나 이에 제한되지 않는다. 일부 구현양태에서, 대상체는 인간이다. 일부 실시형태에서, 대상체는 의사의 관리 하에 있는 환자이다.
- [0019] 본 개시내용은 대상체에게 ERAP2 억제제를 투여하는 것을 포함하여, 면역 장애를 갖는 대상체를 치료하는 방법

을 제공한다. 일부 구현양태에서, 면역 장애는 MHC-1-병증이다. 일부 구현양태에서, 면역 장애는 MHC-1I-병증이다. 일부 구현양태에서, MHC-1-병증은 산탄 맥락망막병증(BSCR), 강직성 척추염(AS), 포도막염과 결합된 건선 또는 소아 특발성 관절염(JIA)이다. 일부 구현양태에서, MHC-1-병증은 BSCR이다. 일부 구현양태에서, MHC-1-병증은 AS이다. 일부 구현양태에서, MHC-1-병증은 포도막염과 결합된 건선이다. 일부 구현양태에서, MHC-1-병증은 JIA이다.

[0020] 일부 구현양태에서, MHC-1-병증은 BSCR이다. 일부 구현양태에서, 방법은 대상체로부터 수득한 생물학적 샘플에서 HLA-Aw19 대립유전자의 존재 또는 부재를 검출하는 것을 추가로 포함한다. 일부 구현양태에서, 대상체는 HLA-Aw19⁺이다. 일부 구현양태에서, 대상체는 HLA-A29⁺, HLA-A30⁺, HLA-A31⁺, 또는 HLA-A33⁺ 또는 이들의 임의의 조합이거나 또는 그러한 것으로 의심된다. 일부 구현양태에서, 상기 방법은 대상체가 HLA-Aw19 대립형질의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 단계를 추가로 포함한다. 일부 구현양태에서, 대상체는 HLA-Aw19의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-Aw19의 2개 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-A29⁺/HLA-A30⁺이다. 일부 구현양태에서, 대상체는 HLA-A29⁺/HLA-A31⁺이다. 일부 구현양태에서, 대상체는 HLA-A29⁺/HLA-A33⁺이다.

[0021] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29⁺가 아니다.

[0022] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29, HLA-A30, HLA-A31 또는 HLA-A33 중 적어도 임의의 2개의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29, HLA-A30, HLA-A31 또는 HLA-A33 중 적어도 임의의 3개의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29, HLA-A30, HLA-A31 또는 HLA-A33 모두의 하나의 카피를 갖는다.

[0023] 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A30의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A31의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A33의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A30 및 HLA-A31의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A30 및 HLA-A33의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A31 및 HLA-A33의 하나의 카피를 갖는다.

[0024] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 1개의 카피 및 HLA-A30의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A30의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 1개의 카피 및 HLA-A33의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 1개의 카피 및 HLA-A31의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 1개 카피 및 HLA-A33의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A31의 1개의 카피 및 HLA-A33의 2개의 카피를 갖는다.

[0025] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 2개의 카피 및 HLA-A30의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 2개의 카피 및 HLA-A31의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 2개의 카피 및 HLA-A33의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 2개의 카피 및 HLA-A31의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 2개의 카피 및 HLA-A33의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A31의 2개의 카피 및 HLA-A33의 1개의 카피를 갖는다.

[0026] 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A29의 2개 카피 및 HLA-A30의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A29의 2개 카피 및 HLA-A31의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A29의 2개 카피 및 HLA-A33의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A30의 2개 카피 및 HLA-A31의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A30의 2개의 카피 및 HLA-A33의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A31의 2개 카피 및 HLA-A33의 2개 카피를 갖는다.

[0027] 일부 구현양태에서, 상기 방법은 대상체에게 HLA-Aw19 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-Aw19 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-A29 항체를 포함한다. 일부 구현

양태에서, HLA-Aw19 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-Aw19에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA(shRNA)를 포함한다. 일부 구현양태에서, HLA-Aw19는 HLA-A29이다.

[0028] 일부 구현양태에서, MHC-1-병증은 AS이다. 일부 구현양태에서, 방법은 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 또는 HLA-B40의 존재 또는 부재를 검출하는 것을 추가로 포함한다. 일부 구현양태에서, 대상체는 HLA-B27⁺이거나 그러한 것으로 의심된다. 일부 구현양태에서, 대상은 HLA-B40⁺이거나 그러한 것으로 의심된다. 일부 구현양태에서, 방법은 대상체가 HLA-B27 또는 HLA-B40의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 단계를 추가로 포함한다. 일부 구현양태에서, 대상체는 HLA-B27 또는 HLA-B40의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-B27 또는 HLA-B40의 2개 카피를 갖는다. 일부 구현양태에서, 상기 방법은 대상체에게 HLA-B27 억제제 또는 HLA-B40 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제 또는 HLA-B40 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-B27 항체 또는 항-HLA-B40 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제 또는 HLA-B40 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27 또는 HLA-B40에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다.

[0029] 일부 구현양태에서, MHC-1-병증은 포도막염과 결합된 건선이다. 특정 구현양태에서, 포도막염은 후방 포도막염이다. 일부 구현양태에서, 방법은 대상체로부터 수득한 생물학적 샘플에서 HLA-B27의 존재 또는 부재를 검출하는 것을 추가로 포함한다. 일부 구현양태에서, 대상체는 HLA-B27⁺이거나 그러한 것으로 의심된다. 일부 구현양태에서, 방법은 대상체가 HLA-B27의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 단계를 추가로 포함한다. 일부 구현양태에서, 대상체는 HLA-B27의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-B*51의 2개 카피를 갖는다. 일부 구현양태에서, 방법은 대상체에게 HLA-B27 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-B27 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다.

[0030] 일부 구현양태에서, MHC-1-병증은 JIA이다. 일부 구현양태에서, 방법은 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 및/또는 DRB1의 존재 또는 부재를 검출하는 것을 추가로 포함한다. 일부 구현양태에서, 대상체는 HLA-B27⁺ 및/또는 DRB1⁺이거나 그러한 것으로 의심된다. 일부 구현양태에서, 방법은 대상체가 HLA-B27 및/또는 DRB1의 카피를 1개 또는 2개 가지고 있는지 여부를 결정하는 단계를 추가로 포함한다. 일부 구현양태에서, 대상체는 HLA-B27 및/또는 DRB1의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-B27 및/또는 DRB1의 2개 카피를 갖는다. 일부 구현양태에서, 방법은 대상체에게 HLA-B27 억제제 및/또는 DRB1 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제 및/또는 DRB1 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-B27 항체 또는 항-DRB1 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제 및/또는 DRB1 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27 및/또는 DRB1에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다.

[0031] 일부 구현양태에서, ERAP2 억제제는 소분자 분해제, 단백질분해-표적 키메라, 면역조절 약물 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 안티센스 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 siRNA를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 shRNA를 포함한다. 일부 구현양태에서, ERAP2 억제제는 항-ERAP2 항체를 포함한다. 일부 구현양태에서, ERAP2 억제제는 슈도펩티드(pseudopeptide)를 포함한다. 일부 구현양태에서, 슈도펩티드는 포스피닉(phosphinic) 슈도펩티드이다. 일부 구현양태에서, 포스피닉 슈도펩티드는 DG002 또는 DG013이다(Zervoudi et al., Proc. Natl. Acad. Sci. USA, 2013, 110, 19890-19895). 일부 구현양태에서, 포스피닉 슈도펩티드는 DG002이다. 일부 구현양태에서, 포스피닉 슈도펩티드는 DG013이다. 일부 구현양태에서, ERAP2 억제제는 소분자를 포함한다. 일부 구현양태에서, ERAP2 억제제는 화합물 4, 화합물 15, 화합물 16, 화합물 5, 또는 화합물 5의 유사체이며, 이는 ERAP1보다 ERAP2에 대한 향상된 선택성에 대해 스크리닝된 약물-유사 카복실산 및 생동배체(bioisoster)이다(Medve et al., European Journal of Medicinal Chemistry, 2021, 211, 113053). 일부 구현양태에서, ERAP2 억제제는 ERAP1보다 ERAP2에 대해 더 높은 친화도를 갖는 포스폰산 또는 포스핀산 화합물이다(Weglarz-Tomczak et al., Bioorg. Med. Chem. Lett., 2016, 26, 4122-4126). 추가적인 ERAP2 억제제는 문헌에 기재되어 있다(Georgiadis et al., Curr. Medic. Chem., 2019, 26, 2715-

2729).

- [0032] 본원에 기재된 임의의 구현양태에서, 본원에 기재된 임의의 억제제 또는 다른 제제는 항체-약물-접합체(ADC)의 성분을 형성할 수 있다. 예를 들어, ERAP2 억제제는 항체 또는 이의 항원 결합 단편에 접합될 수 있다. 억제제는 소분자 분해제, 단백질분해-표적 키메라, 면역조절 약물 또는 억제성 핵산 분자를 포함할 수 있다.
- [0033] 본 개시내용은 또한 MHC-1-병증을 갖는 대상체를 치료하는 방법을 제공한다. 일부 구현양태에서, 방법은 대상체가 i) MHC-1-병증-관련 HLA 유전자형; 및 ii) 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 포함하는지 여부를 결정하기 위해 대상체로부터의 생물학적 샘플에 대해 검정을 수행하거나 수행했던 것을 포함한다. 일부 구현양태에서, 방법은 대상체에게 치료적 유효량의 ERAP2 억제제를 투여하는 것을 포함하며, 여기서 대상체는 MHC-1-병증-관련 HLA 유전자형 및 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 모두 포함한다. MHC-1-병증-관련 HLA 유전자형 및 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자 모두의 존재는 대상체가 ERAP2를 억제하여 MHC-1-병증을 치료할 후보임을 나타낸다.
- [0034] 일부 구현양태에서, MHC-1-병증은 BSCR이고 MHC-1-병증-관련 HLA 유전자형은 HLA-Aw19 대립유전자를 포함한다. 일부 구현양태에서, HLA-Aw19 대립유전자는 HLA-A29 대립유전자, HLA-A30 대립유전자, HLA-A31 대립유전자 또는 HLA-A33 대립유전자 또는 이들의 임의의 조합이다. 일부 구현양태에서, 대상체는 HLA-Aw19 대립유전자의 단일 카피를 갖는다. 일부 구현양태에서, HLA-Aw19 대립유전자는 HLA-A29 대립유전자를 포함한다. 일부 구현양태에서, HLA-Aw19 대립유전자는 HLA-A30 대립유전자를 포함한다. 일부 구현양태에서, HLA-Aw19 대립유전자는 HLA-A31 대립유전자를 포함한다. 일부 구현양태에서, HLA-Aw19 대립유전자는 HLA-A33 대립유전자를 포함한다. 일부 구현양태에서, 대상체는 HLA-Aw19 대립유전자의 2개 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-A29⁺/HLA-A30⁺이거나 그러한 것으로 의심된다. 일부 구현양태에서, 대상체는 HLA-A29⁺/HLA-A31⁺이거나 또는 그러한 것으로 의심된다. 일부 구현양태에서, 대상체는 HLA-A29⁺/HLA-A33⁺이거나 그러한 것으로 의심된다.
- [0035] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29⁺가 아니다.
- [0036] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29, HLA-A30, HLA-A31 또는 HLA-A33 중 적어도 임의의 2개의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29, HLA-A30, HLA-A31 또는 HLA-A33 중 적어도 임의의 3개의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29, HLA-A30, HLA-A31 또는 HLA-A33 모두의 하나의 카피를 갖는다.
- [0037] 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A30의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A31의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A33의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A30 및 HLA-A31의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A30 및 HLA-A33의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A31 및 HLA-A33의 하나의 카피를 갖는다.
- [0038] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 1개의 카피 및 HLA-A30의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A30의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 1개의 카피 및 HLA-A33의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 1개의 카피 및 HLA-A31의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 1개 카피 및 HLA-A33의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A31의 1개의 카피 및 HLA-A33의 2개의 카피를 갖는다.
- [0039] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 2개의 카피 및 HLA-A30의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 2개의 카피 및 HLA-A31의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 2개의 카피 및 HLA-A33의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 2개의 카피 및 HLA-A31의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 2개의 카피 및 HLA-A33의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A31의 2개의 카피 및 HLA-A33의 1개의 카피를 갖는다.
- [0040] 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A29의 2개 카피 및 HLA-A30의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A29의 2개 카

피 및 HLA-A31의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A29의 2개 카피 및 HLA-A33의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A30의 2개 카피 및 HLA-A31의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 2개의 카피 및 HLA-A31의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A31의 2개 카피 및 HLA-A33의 2개 카피를 갖는다.

[0041] 일부 구현양태에서, 방법은 대상체에게 HLA-Aw19 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-Aw19 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-A29 항체를 포함한다. 일부 구현양태에서, HLA-Aw19 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-Aw19에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다. 일부 구현양태에서, HLA-Aw19는 HLA-A29이다.

[0042] 일부 구현양태에서, MHC-1-병증은 AS이고 MHC-1-병증 관련 HLA 유전자형은 HLA-B27 대립유전자 또는 HLA-B40 대립유전자를 포함한다. 일부 구현양태에서, 대상체는 HLA-B27 또는 HLA-B40의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-B27 또는 HLA-B40의 2개 카피를 갖는다. 일부 구현양태에서, 상기 방법은 대상체에게 HLA-B27 억제제 또는 HLA-B40 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제 또는 HLA-B40 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-B27 항체 또는 항-HLA-B40 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제 또는 HLA-B40 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27 또는 HLA-B40에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다.

[0043] 일부 구현양태에서, MHC-1-병증은 포도막염과 결합된 건선이고 MHC-1-병증-관련 HLA 유전자형은 HLA-B27 대립유전자를 포함한다. 특정 구현양태에서, 포도막염은 후방 포도막염이다. 일부 구현양태에서, 대상체는 HLA-B27의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-B27의 2개 카피를 갖는다. 일부 구현양태에서, 방법은 대상체에게 HLA-B27 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-B27 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다.

[0044] 일부 구현양태에서, MHC-1-병증은 JIA이고 MHC-1-병증-관련 HLA 유전자형은 HLA-B27 및/또는 DRB1을 포함한다. 일부 구현양태에서, 대상체는 HLA-B27 및/또는 DRB1의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-B27 및/또는 DRB1의 2개 카피를 갖는다. 일부 구현양태에서, 방법은 대상체에게 HLA-B27 억제제 및/또는 DRB1 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제 및/또는 DRB1 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-B27 항체 및/또는 DRB1 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제 및/또는 DRB1 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27 또는 DRB1에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다.

[0045] 본원에 기재된 임의의 구현양태에서, 핵산 분자는 게놈 DNA, mRNA, 또는 mRNA로부터 수득된 cDNA를 포함한다. 일부 구현양태에서, 핵산 분자는 게놈 DNA를 포함한다. 일부 구현양태에서, 핵산 분자는 mRNA를 포함한다. 일부 구현양태에서, 핵산 분자는 mRNA로부터 얻은 cDNA를 포함한다.

[0046] 본원에 기재된 임의의 구현양태에서, ERAP2 억제제는 소분자 분해제, 단백질 분해-표적 키메라, 면역조절 약물 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 안티센스 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 siRNA를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 shRNA를 포함한다. 일부 구현양태에서, ERAP2 억제제는 항-ERAP2 항체를 포함한다. 일부 구현양태에서, ERAP2 억제제는 슈도캡티드를 포함한다. 일부 구현양태에서, 슈도캡티드는 포스포닉 슈도캡티드이다. 일부 구현양태에서, 포스포닉 슈도캡티드는 DG002 또는 DG013이다. 일부 구현양태에서, ERAP2 억제제는 소분자를 포함한다.

[0047] HLA-클래스-I 항체는 달성된 항원/대립유전자 특이성의 정도가 다른 수많은 방법론에 의해 생성될 수 있으며 생체 외 검정에 사용되는 것으로 보고된다. HLA-B27 항체는 다양한 방법으로 생성할 수 있다. 또한, HLA-B27 유세포 분석 스크리닝을 위한 3개의 상업적으로 이용가능한 항체에는 각각 다른 HLA-B 항원/대립유전자에 대해 서로 다른 수준의 교차 반응성을 나타내는 것으로 밝혀진 모노클로날 마우스 항-인간 ABC-m3, FD705 및 GS145.2가 포함된다(Levering et al., Cytometry B Clin. Cytom., 2003, 54, 28-38).

- [0048] 일부 구현양태에서, 대상체가 MHC-1-병증-관련 및/또는 MHC-1I-병증-관련 HLA 유전자형 및 기능적 ERAP2 단백질, 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 포함하는지 여부를 결정하기 위한 검정은 유전자형 검정 또는 시퀀싱 검정이다. 일부 구현양태에서, 기능적 ERAP2 단백질을 암호화하는 핵산 분자는 게놈 DNA, mRNA, 또는 mRNA로부터 수득한 cDNA를 포함한다. ERAP2 단백질 또는 핵산 분자에 대한 야생형 서열, 또는 활성이 감소되었거나 없는 변이체 ERAP2 단백질 또는 핵산 분자의 공개된 서열에 대해 대상체로부터의 샘플에서 ERAP2 단백질의 뉴클레오타이드 또는 단백질 서열을 비교함으로써, 대상체가 기능적 ERAP2 단백질, 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 포함하는지 여부를 결정할 수 있다. 또한, 개별 ERAP2 단백질이 생물학적 활성을 가질 수 있지만, ERAP2 단백질의 전반적인 기능은 감소된 수준의 발현으로 인해 기능하지 않을 수 있다. 따라서, 본원에서 사용되는 바와 같이, ERAP2 단백질은 생물학적 활성이 결여되거나 감소되었기 때문에 또는 발현 수준이 감소되었기 때문에, ERAP2 단백질은 기능적이지 않은 것으로 결정될 수 있다.
- [0049] 대상체가 MHC-1-병증-관련 및/또는 MHC-1I-병증-관련 HLA 유전자형 및/또는 기능적 ERAP2 단백질, 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 갖는지 여부에 대한 결정은 대상체의 생물학적 샘플에서 본원에 기술된 임의의 방법에 의해 수행될 수 있다. 일부 구현양태에서, 이들 방법은 *생체 외*에서 수행될 수 있다. 일부 구현양태에서, 이들 방법은 *제자리*(in situ)에서 수행될 수 있다. 일부 구현양태에서, 이러한 방법은 *생체 내*에서 수행될 수 있다. 임의의 이러한 구현양태에서, 핵산 분자는 대상체로부터 수득한 생물학적 샘플 내에 존재할 수 있다.
- [0050] 생물학적 샘플은 대상체로부터의 임의의 세포, 조직, 또는 생물학적 유체로부터 유래할 수 있다. 생물학적 샘플은 골수 샘플, 중앙 생검, 미세 바늘 흡입물, 또는 혈액, 치은열구액, 혈장, 혈청, 림프, 복수, 낭포액, 또는 소변과 같은 체액 샘플과 같은 임의의 임상적으로 관련 조직을 포함할 수 있다. 일부 경우에, 샘플은 협측 면봉을 포함한다. 본원에 개시된 방법에 사용되는 생물학적 샘플은 검정 형식, 검출 방법 속성, 및 샘플로서 사용된 조직, 세포, 또는 추출물에 기반하여 달라질 수 있다. 생물학적 샘플은 이용될 검정에 따라서 상이하게 가공될 수 있다. 예를 들어, 임의의 특정 핵산 분자를 검출할 때, 특정 핵산 분자에 대한 생물학적 샘플을 분리하거나 농축하도록 설계된 예비 처리가 사용될 수 있다. 다양한 기술이 이러한 목적을 위해 사용될 수 있다. mRNA 분자의 존재 또는 수준 또는 특정 게놈 DNA 유전자좌의 존재를 검출하기 위한 다양한 방법이 사용될 수 있다.
- [0051] 일부 구현양태에서, 생물학적 샘플은 세포 또는 세포 용해물을 포함한다. 이러한 방법은, 예를 들어 대상체로부터 게놈 핵산 분자 또는 mRNA 분자를 포함하는 생물학적 샘플을 수득하는 것, 및 mRNA인 경우 임의로 mRNA를 cDNA로 역전사시키는 것을 포함할 수 있다. 일부 구현양태에서, 방법은 *생체 외* 방법이다. 일부 실시형태에서, 예시에는 RNA 시퀀싱(RNA-Seq)을 포함한다. 일부 실시형태에서, 검정은 또한 역전사효소 중합효소 연쇄 반응(RT-PCR)에 의한 것과 같이 cDNA로 mRNA를 역전사하는 단계를 포함한다.
- [0052] 핵산 시퀀싱 기술의 예시적인 예는 쉐 종결자(Sanger) 시퀀싱 및 염료 종결자 시퀀싱을 포함하나, 이에 제한되지 않는다. 다른 방법은 정제된 DNA, 증폭된 DNA 및 고정된 세포 제제에 대한 표지된 프라이머 또는 프로브의 사용을 포함한, 시퀀싱이 아닌 핵산 혼성화 방법과 관계된다(형광 제자리 혼성화(FISH)). 일부 방법에서, 표적 핵산 분자는 검출 이전에 또는 검출과 동시에 증폭될 수 있다. 핵산 증폭 기술의 설명적인 예는 중합효소 연쇄 반응(PCR), 리가제 연쇄 반응(LCR), 가닥 변위 증폭(SDA) 및 핵산 서열 기반의 증폭(NASBA)을 포함하나, 이에 제한되지 않는다. 일부 방법에서, 표적 핵산 분자는 탐지에 앞서 또는 이와 동시에 증폭될 수 있다. 핵산 증폭 기술의 설명적인 예는 중합효소 연쇄 반응(PCR), 리가제 연쇄 반응(LCR), 가닥 변위 증폭(SDA) 및 핵산 서열 기반의 증폭(NASBA)을 포함하나, 이에 제한되지 않는다. 다른 방법에는 리가제 연쇄 반응, 가닥 변위 증폭 및 호열성 SDA(tSDA)가 포함되지만 이에 제한되지는 않는다.
- [0053] 본원에 기재된 임의의 치료제(ERAP2 억제제 및/또는 HLA 억제제 포함)의 투여는 의료 전문가에 의해 결정되는 치료 유효량일 수 있다. 임의의 치료제의 투여는, 예를 들어 1일, 2일, 3일, 5일, 1주, 2주, 3주, 1개월, 5주, 6주, 7주, 8주, 2개월 또는 3개월 후에 반복될 수 있다. 반복된 투여는 동일한 용량 또는 상이한 용량일 수 있다. 투여는 1 회, 2 회, 3 회, 4 회, 5 회, 6 회, 7 회, 8 회, 9 회, 10 회 또는 그 이상 반복될 수 있다. 예를 들어, 특정 투여 요법에 따라 대상체는 장기간, 예컨대, 예를 들어, 6 개월 또는 1 년 이상 동안 요법을 받을 수 있다.
- [0054] 임의의 치료제의 투여는 비경구, 정맥내, 경구, 피하, 동맥내, 두개내, 척수강내, 복강내, 국소, 비강내, 관절내, 유리체강내, 전안방내, 망막하, 맥락막위 또는 근육내를 포함하나, 이로 제한되지 않는다.
- [0055] 투여를 위한 약학적 조성물은 바람직하게는 멸균되고, 실질적으로 등장성이며, GMP 조건하에서 제조된다. 제약 조성물은 단위 투여 형태(즉, 단일 투여를 위한 투여량)로 제공될 수 있다. 제약 조성물은 하나 이상의 생리학

적 및 제약상 허용되는 담체, 희석제, 부형제 또는 보조제를 사용하여 제형화될 수 있다. 제제는 선택된 투여 경로에 따라 달라진다. 용어 "약제학적으로 허용되는"은 담체, 희석제, 부형제 또는 보조제가 제형의 다른 성분과 친화성이고 수용자에게 실질적으로 해롭지 않다는 것을 의미한다.

[0056] 본원에 사용된 용어 "치료하다", "치료하는" 및 "치료", 및 "예방하다", "예방하는" 및 "예방"은 원하는 생물학적 반응, 예컨대, 각자 치료적 및 예방적 효과를 이끌어내는 것을 지칭한다. 일부 구현양태에서, 치료적 효과는 MHC-1-병증 및/또는 MHC-1I-병증의 감소/약화, MHC-1-병증 및/또는 MHC-1I-병증 중증도의 감소/약화(예를 들어, MHC-1-병증 및/또는 MHC-1I-병증의 발생 감소 또는 억제), 증상 및 MHC-1-병증-관련 효과 및/또는 MHC-1I-병증-관련 효과에서의 감소/약화, 증상 및 MHC-1-병증-관련 효과 및/또는 MHC-1I-병증-관련 효과의 개시를 지연, MHC-1-병증-관련 효과 및/또는 MHC-1I-병증-관련 효과의 증상의 중증도 감소, 급성 에피소드의 중증도 감소, 증상 및 MHC-1 병증-관련 효과 및/또는 MHC-1I-병증-관련 효과에서 횡수 감소, 증상 및 MHC-1-병증-관련 효과 및/또는 MHC-1I-병증-관련 효과의 잠복기 감소, 증상 및 MHC-1-병증-관련 효과 및/또는 MHC-1I-병증-관련 효과의 완화, 2차 증상 감소, 2차 감염 감소, MHC-1-병증 및/또는 MHC-1I-병증으로의 재발 방지, 재발 에피소드의 수 또는 빈도 감소, 증상 에피소드 사이의 잠복기 증가, 지속적인 진행까지의 시간 증가, 회복 속도 증가, 또는 대체 치료제에 대한 효능 증가 또는 내성 감소, 및/또는 제제 또는 제제를 포함하는 조성물의 투여 후 대상체의 생존 시간 증가 중 하나 이상을 포함한다. 예방 효과는 MHC-1-병증 및/또는 MHC-1I-병증 발생/진행의 완전하거나 부분적인 회피/억제 또는 지연(예를 들어, 완전하거나 부분적인 회피/억제 또는 지연), 및 치료 프로토콜의 투여 후 영향을 받는 대상체의 증가된 생존 시간을 포함할 수 있다. MHC-1-병증 및/또는 MHC-1I-병증의 치료는 임의의 임상 단계 또는 징후에서 임의의 형태의 MHC-1-병증 및/또는 MHC-1I-병증을 갖는 것으로 이미 진단된 대상체의 치료를 포함하며, MHC-1-병증 및/또는 MHC-1I-병증의 증상 또는 징후의 개시 또는 진행 또는 악화 또는 변질의 지연, 및/또는 MHC-1-병증 및/또는 MHC-1I-병증의 중증도의 예방 및/또는 감소를 포함한다.

[0057] 일부 구현양태에서, ERAP2 안티센스 핵산 분자는 서열번호 1 내지 858에 의해 나타난 뉴클레오티드 서열을 포함하거나 이로 이루어진다. 일부 구현양태에서, ERAP2 siRNA 분자는 서열 번호: 859 내지 2748(예를 들어, 센스 가닥은 예를 들어, 서열 번호 859이고 상응하는 안티센스 가닥은 서열번호 860이고; 센스 가닥은 예를 들어 서열번호 861이고 상응하는 안티센스 가닥은 예를 들어 서열번호 862이고; 센스 가닥은 예를 들어 서열번호 2747 이고 상응하는 안티 센스 가닥은 예를 들어 서열번호 2748이다; 등).

[0058] 일부 구현양태에서, HLA-A 안티센스 핵산 분자는 서열번호 2749 내지 2763으로 표시되는 뉴클레오티드 서열을 포함하거나 이로 이루어진다. 일부 구현양태에서, HLA-A siRNA 분자는 서열 번호 2764 내지 2777로 표시되는 뉴클레오티드 서열(연속으로 제시되는 센스 및 안티센스 가닥)을 포함하거나 이로 구성된다(예를 들어, 센스 가닥은 예를 들어, 서열 번호 2764이고 상응하는 안티센스 가닥은 서열번호 2765이고; 센스 가닥은 예를 들어 서열번호 2766이고 상응하는 안티센스 가닥은 서열번호 2767이고; 센스 가닥은 예를 들어 서열번호 2776이고 상응하는 안티센스 가닥은 2777이다; 등).

[0059] 일부 구현양태에서, HLA-B 안티센스 핵산 분자는 서열번호 2778 및 서열번호 2779로 표시되는 뉴클레오티드 서열을 포함하거나 이로 구성된다. 일부 구현양태에서, HLA-B siRNA 분자는 서열 번호 2780 내지 2783으로 표시되는 임의의 뉴클레오티드 서열(연속으로 제시되는 센스 및 안티센스 가닥)을 포함하거나 이로 이루어진다(예를 들어, 센스 가닥은 예를 들어, 서열번호 2780이고 상응하는 안티센스 가닥은 서열번호 2781이고, 센스 가닥은 예를 들어 서열번호 2783이고 상응하는 안티센스 가닥은 서열번호 2783이다).

[0060] 일부 구현양태에서, HLA-C 안티센스 핵산 분자는 서열번호 2784 및 서열번호 2785로 표시되는 뉴클레오티드 서열을 포함하거나 이로 구성된다. 일부 구현양태에서, HLA-C siRNA 분자는 서열번호 2786 및 서열번호 2787로 표시되는 임의의 뉴클레오티드 서열(연속으로 제시되는 센스 및 안티센스 가닥)을 포함하거나 이로 이루어진다.

[0061] 일부 구현양태에서, B27 안티센스 핵산 분자는 서열번호 2788 내지 3132로 표시되는 뉴클레오티드 서열을 포함하거나 이로 구성된다. 일부 구현양태에서, B27 siRNA 분자는 서열 번호 3133 내지 3870(예를 들어, 센스 가닥은 예를 들어, 서열 번호 대응하는 안티센스 가닥은 서열번호 3133이고 상응하는 안티센스 가닥은 서열번호 3134이고; 센스 가닥은 예를 들어 서열번호 3135이고 상응하는 안티센스 가닥은 서열번호 3136이고; 센스 가닥은 예를 들어 서열번호 3869이고 상응하는 안티센스 가닥은 서열번호 3870이다; 등).

[0062] 일부 구현양태에서, A29 안티센스 핵산 분자는 서열번호 3871 내지 4145로 표시되는 뉴클레오티드 서열을 포함하거나 이로 구성된다. 일부 구현양태에서, A29 siRNA 분자는 서열 번호 4146 내지 4755(예를 들어, 센스 가닥은 예를 들어, 서열 번호 4146이고 상응하는 안티센스 가닥은 서열번호 4147이고; 센스 가닥은 예를 들어 서열번호 4148이고 상응하는 안티센스 가닥은 서열번호 4149이고; 센스 가닥은 예를 들어 서열번호 4754이고 상응하

는 안티센스 가닥은 서열번호 4755이다; 등).

- [0063] 본원에 개시된 억제성 핵산 분자는 RNA, DNA, 또는 양쪽 RNA 및 DNA를 포함할 수 있다. 억제성 핵산 분자는 이중 핵산 서열에, 예컨대 벡터에서, 또는 이중 표지에 또한 결합 또는 융합될 수 있다. 예를 들어, 본원에 개시된 억제성 핵산 분자는 벡터 내에서 또는 억제성 핵산 분자 및 이중 핵산 서열을 포함하는 외인성 기증자 서열로서 있을 수 있다. 억제성 핵산 분자는 이중 표지에 또한 결합 또는 융합될 수 있다. 표지는 직접적으로 검출 가능할 수 있거나(예컨대, 예를 들어, 형광단) 간접적으로 검출가능할 수 있다(예컨대, 예를 들어, 합텐, 효소, 또는 형광단 퀀처). 이러한 표지는 분광학적, 광화학적, 생화학적, 면역화학적, 또는 화학적 수단에 의해 검출 가능할 수 있다. 이러한 표지는, 예를 들어, 방사성표지, 안료, 염료, 스핀 표지, 및 형광성 표지를 포함한다. 표지는 또한, 예를 들어, 화학발광성 물질; 금속-함유 물질; 또는 신호의 효소-의존적 이차 생성이 발생하는 경우, 효소일 수 있다. 용어 "표지"는 접합된 분자가, 기질과 함께 후속적으로 첨가될 때, 검출가능한 신호를 생성하는데 사용되도록 접합된 분자에 선택적으로 결합할 수 있는 "태그" 또는 합텐을 또한 지칭할 수 있다. 예를 들어, 비오틴은 태그에 결합하기 위해 호스래디쉬 퍼옥시데이티(HRP)의 아비딘 또는 스트렙타비딘 접합체와 함께 태그로서 사용될 수 있고, HRP의 존재를 검출하기 위해 열량측정 기질(예컨대, 예를 들어, 테트라메틸벤지딘(TMB)) 또는 형광발생 기질을 사용하여 시험될 수 있다. 정제를 용이하게 하기 위해 태그로서 사용될 수 있는 예시적인 표지는 myc, HA, FLAG 또는 3XFLAG, 6XHis 또는 폴리히스티딘, 글루타티온-S-트랜스퍼라제(GST), 말토스 결합 단백질, 에피토프 태그, 또는 면역글로불린의 Fc 부분을 포함하나 이에 제한되지 않는다. 다수의 표지는, 예를 들어 입자, 형광단, 합텐, 효소 및 이들의 열량, 형광 및 화학발광 기질 및 기타 표지를 포함한다.
- [0064] 개시된 억제성 핵산 분자는, 예를 들어 뉴클레오타이드 또는 비-천연 또는 변형된 뉴클레오타이드, 예컨대 뉴클레오타이드 유사체 또는 뉴클레오타이드 치환체를 포함할 수 있다. 이러한 뉴클레오타이드는 변형된 염기, 당 또는 포스페이트기를 함유하거나 구조에 비-천연 모이어티가 혼입된 뉴클레오타이드를 포함한다. 비-천연 뉴클레오타이드의 예는 디데옥시뉴클레오타이드, 비오틴닐화, 아민화, 탈아민화, 알킬화, 벤질화 및 형광단-표지 뉴클레오타이드를 포함하나 이에 제한되지 않는다.
- [0065] 본원에 개시된 억제성 핵산 분자는 또한 하나 이상의 뉴클레오타이드 유사체 또는 치환체를 포함할 수 있다. 뉴클레오타이드 유사체는 염기, 당 또는 포스페이트 모이어티에 대한 변형을 함유하는 뉴클레오타이드이다. 염기 모이어티에 대한 개질은, A, C, G, 및 T/U, 뿐만 아니라 상이한 퓨린 또는 피리딘 염기, 예컨대 슈도우리딘, 우라실-5-일, 하이포산틴-9-일(I), 및 2-아미노아데닌-9-일의 자연적 및 합성적 개질을 포함하나, 이에 제한되지 않는다. 변형된 염기는, 비제한적으로,
- [0066] 5-메틸시토신(5-me-C), 5-하이드록시메틸 시토신, 크산틴, 하이포크산틴,
- [0067] 2-아미노아데닌, 아데닌 및 구아닌의 6-메틸 및 기타 알킬 유도체, 아데닌 및 구아닌의 2-프로필 및 기타 알킬 유도체, 2-티오우라실, 2-티오티민 및 2-티오시토신, 5-할로우라실 및 시토신, 5-프로피닐 우라실 및 시토신, 6-아조 우라실, 시토신 및 티민, 5-우라실(슈도우라실), 4-티오우라실, 8-할로, 8-아미노, 8-티올, 8-티오알킬, 8-하이드록실 및 기타 8-치환 아데닌 및 구아닌, 5-할로(예컨대, 예를 들어, 5-브로모), 5-트리플루오로메틸 및 기타 5-치환 우라실 및 시토신, 7-메틸구아닌, 7-메틸아데닌, 8-아자구아닌, 8-아자아데닌, 7-테아자구아닌, 7-테아자아데닌, 3-테아자구아닌 및 3-테아자아데닌을 포함한다.
- [0068] 뉴클레오타이드 유사체는 또한 당 모이어티의 개질을 포함할 수 있다. 당 모이어티에 대한 변형은 리보스 및 데옥시 리보스의 천연 변형뿐만 아니라 합성 변형을 포함하나 이에 제한되지 않는다. 당 변형은 2' 위치에서 다음 변형을 포함하나 이에 제한되지 않으며: OH; F; O-, S-, 또는 N-알킬; O-, S-, 또는 N-알케닐;
- [0069] O-, S- 또는 N-알킬닐; 또는 O-알킬-O-알킬, 여기서 알킬, 알케닐, 및 알키닐은 치환 또는 비치환된 C_{1-10} 알킬 또는 C_{2-10} 알케닐 및 C_{2-10} 알키닐일 수 있다. 예시적인 2' 당 변형은 또한 $-O[(CH_2)_nO]_mCH_3$, $-O(CH_2)_nOCH_3$, $-O(CH_2)_nNH_2$, $-O(CH_2)_nCH_3$, $-O(CH_2)_nONH_2$ 및 $-O(CH_2)_nON[(CH_2)_nCH_3]_2$ 를 포함하나 이에 제한되지 않으며, 여기서 n 및 m은 독립적으로 1 내지 약 10이다. 2' 위치에서 다른 변형은 C_{1-10} 알킬, 치환된 저급 알킬, 알카릴, 아르알킬, O-알카릴 또는 O-아르알킬, SH, SCH₃, OCN, Cl, Br, CN, CF₃, OCF₃, SOCH₃, SO₂CH₃, ONO₂, NO₂, N₃, NH₂, 헤테로 사이클로알킬, 헤테로사이클로알카릴, 아미노알킬아미노, 폴리알킬아미노, 치환된 실릴, RNA 절단 기, 리포터 기, 인터칼레이트, 올리고뉴클레오타이드의 약동학적 특성을 개선하기 위한 기, 또는 올리고뉴클레오타이드의 약력학적 특성을 개선하기 위한 기, 및 유사한 특성을 갖는 다른 치환기를 포함하나 이에 제한되지 않는다. 유사한 변형은 또한 당의 다른 위치, 특히 3' 말단 뉴클레오타이드 또는 2'-5' 연결 올리고뉴클레오타이드의 당의 3' 위치와 5' 말단 뉴클레오타이드의 5' 위치에 생길 수도 있다. 변형된 당은 또한 브리지 고리 산소에 대한 변형, 예

컨대 CH_2 및 S를 함유한 것들을 포함할 수도 있다. 뉴클레오타이드 당 유사체는 또한 펜토푸라노실 당 대신에 당 모사체, 예컨대 사이클로부틸 모이어티를 가질 수도 있다.

- [0070] 뉴클레오타이드 유사체는 또한 포스페이트 모이어티에서 변형될 수 있다. 변형된 포스페이트 모이어티는 2 개의 뉴클레오타이드 사이의 연결(linkage)이 포스포로티오에이트, 키랄 포스포로티오에이트, 포스포로디티오에이트, 포스포트리에스테르, 아미노알킬포스포트리에스테르, 메틸 및 3'-알킬렌 포스포네이트 및
- [0071] 키랄 포스페이트를 포함하는 다른 알킬 포스포네이트, 포스포네이트, 3'-아미노 포스포르아미데이트 및 아미노알킬포스포르아미데이트를 포함하는 포스포르아미데이트, 티오노포스포르아미데이트, 티오노알킬포스포네이트, 티오노알킬포스포트리에스테르, 및 보라노포스페이트를 함유하도록 변형될 수 있는 것들을 포함하나 이에 제한되지 않는다. 2개의 뉴클레오타이드 사이의 이러한 포스페이트 또는 변형된 포스페이트 연결은 3'-5' 연결 또는 2'-5' 연결을 통해 이루어질 수 있고, 연결은 3'-5' 내지 5'-3' 또는 2'-5' 내지 5'-2'와 같은 반전 극성(inverted polarity)을 함유할 수 있다. 다양한 염, 혼합된 염 및 유리산 형태도 또한 포함된다. 뉴클레오타이드 치환체에는 펩티드 핵산(PNA)도 포함된다.
- [0072] 일부 구현양태에서, 안티센스 핵산 분자는 갭머이며, 이에 따라 5' 및 3' 단부에서 처음 1개에서 7개의 뉴클레오타이드는 각각 2'-메톡시에틸(2'-MOE) 변형을 갖는다. 일부 구현양태에서, 5' 및 3' 단부에 있는 처음 5개의 뉴클레오타이드는 각각 2'-MOE 변형을 갖는다. 일부 구현양태에서, 5' 및 3' 단부에서 처음 1개에서 7개의 뉴클레오타이드는 RNA 뉴클레오타이드이다. 일부 구현양태에서, 5' 및 3' 단부에서 처음 5개의 뉴클레오타이드는 RNA 뉴클레오타이드이다. 일부 구현양태에서, 뉴클레오타이드 사이의 백본 연결 각각은 포스포로티오에이트 연결이다.
- [0073] 일부 구현양태에서, siRNA 분자는 말단 변형을 갖는다. 일부 구현양태에서, 안티센스 가닥의 5' 단부는 포스포릴화된다. 일부 구현양태에서, 5'-(E)-비닐-포스포네이트와 같이 가수분해될 수 없는 5'-포스페이트 유사체가 사용된다.
- [0074] 일부 구현양태에서, siRNA 분자는 백본 변형을 갖는다. 일부 구현양태에서, 연속적인 리보스 뉴클레오시드를 연결하는 변형된 포스포디에스테르 기는 siRNA의 안정성 및 생체 내 생체이용률을 향상시키는 것으로 나타났다. 포스포디에스테르 연결의 비-에스테르기(-OH, =O)는 황, 붕소, 또는 아세테이트로 대체되어 포스포로티오에이트, 보라노포스페이트 및 포스포노아세테이트 결합을 제공할 수 있다. 또한 포스포디에스테르 기를 포스포트리에스테르로 대체하면 음전하를 제거하여 siRNA의 세포 흡수 및 혈청 성분에 대한 보유를 촉진할 수 있다. 일부 구현양태에서, siRNA 분자는 당 변형을 갖는다. 일부 구현양태에서, 당은 탈양성자화(엑소- 및 엔도뉴클레아제에 의해 촉매되는 반응)되어 2'-하이드록실은 친핵체로 작용하여 포스포디에스테르 결합에서 인접한 인을 공격할 수 있다. 그러한 대안은 2'-O-메틸, 2'-O-메톡시에틸 및 2'-플루오로 변형을 포함한다.
- [0075] 일부 구현양태에서, siRNA 분자는 염기 변형을 갖는다. 일부 구현양태에서, 염기는 슈도우리딘, 5'-메틸시티딘, N6-메틸아데노신, 이노신 및 N7-메틸구아노신과 같은 변형된 염기로 치환될 수 있다.
- [0076] 일부 구현양태에서, siRNA 분자는 지질에 접합된다. 지질은 siRNA의 5' 또는 3' 말단에 접합되어 혈청 지단백질과 연합되도록 함으로써 생체 내 생체이용률을 향상시킬 수 있다. 대표적인 지질은 콜레스테롤 및 비타민 E, 및 팔미테이트 및 토코페롤과 같은 지방산을 포함하지만 이에 제한되지 않는다.
- [0077] 일부 구현양태에서, 대표적인 siRNA는 다음식을 갖는다:
- [0078] 센스: $\text{mN}^*\text{mN}^*/\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}/$
- [0079] $\text{i2FN}/\text{mN}^*/\text{32FN}/$
- [0080] 안티센스: $/\text{52FN}/\text{mN}^*/\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}/$
- [0081] $\text{i2FN}/\text{mN}/\text{i2FN}/\text{mN}^*\text{N}$
- [0082] 여기서: "N"은 염기이고; "2F"는 2'-F 변형이고; "m"은 2'-O-메틸 변형이고, "I"는 내부 염기이고; "*"는 포스포로티오에이트 백본 연결이다.
- [0083] 본 개시내용은 또한 본원에 개시된 임의의 하나 이상의 억제성 핵산 분자를 포함하는 벡터를 제공한다. 일부 구현양태에서, 벡터는 본원에 개시된 임의의 하나 이상의 억제성 핵산 분자 및 이중 핵산을 포함한다. 벡터는 핵산 분자를 전달할 수 있는 바이러스 또는 비바이러스 벡터일 수 있다. 일부 구현양태에서, 벡터는 플라스미드 또는 코스미드(예를 들어, 추가적인 DNA 세그먼트가 결합될 수 있는 원형 이중 가닥 DNA와 같음)이다. 일부 구현양태에서, 벡터는 바이러스 벡터인데, 여기에서 추가적인 DNA 단편들은 바이러스 게놈으로 라이게이션될 수

있다. 발현 벡터는 플라스미드, 코스미드, 레트로바이러스, 아데노바이러스, 아데노-관련 바이러스(AAV), 콜리 플라워 모자이크 바이러스 및 담배 모자이크 바이러스와 같은 식물 바이러스, 효모 인공 염색체(YAC), 엡스타인-바(Epstein-Barr)(EBV)-유래 에피솜 및 당업계에 공지된 다른 발현 벡터를 포함하지만 이에 제한되지 않는다.

[0084] 본 개시내용은 또한 본원에 개시된 임의의 하나 이상의 억제성 핵산 분자를 포함하는 조성물을 제공한다. 일부 구현양태에서, 조성물은 약학적 조성물이다. 일부 구현양태에서, 조성물은 담체 및/또는 부형제를 포함한다. 담체의 예는 폴리(락트산)(PLA) 미소구체, 폴리(D,L-락틱-글리콜-산)(PLGA) 미소구체, 리포솜, 마이셀, 역상마이셀, 지질 코클레이트(cocleate) 및 지질 미세소관을 포함하나, 이에 제한되지 않는다. 담체는 완충된 염 용액, 예컨대 PBS, HBSS 등을 포함할 수 있다. 보유자는 PBS, HBSS 등의 완충 염 용액을 포함할 수 있다.

[0085] 본 개시내용은 또한 MHC-1-병증 및/또는 MHC-1I-병증이 발병할 위험이 증가된 대상체를 확인하는 방법을 제공한다. 상기 방법은 대상체가 i) MHC-1-병증-관련 HLA 유전자형 및/또는 MHC-1I-병증-관련 HLA 유전자형; 및 ii) 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 포함하는지 여부를 결정하기 위해 대상체로부터의 생물학적 샘플에 대해 검정을 수행하거나 수행한 것을 포함한다. 대상체가 MHC-1-병증-관련 HLA 유전자형 및/또는 MHC-1I-병증-관련 HLA 유전자형 및 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 모두 가지고 있는 경우, 대상체는 MHC-1-병증 및/또는 MHC-1I-병증이 발생할 증가된 위험이 있다. 대상체가 MHC-1-병증-관련 HLA 유전자형 및/또는 MHC-1I-병증-관련 HLA 유전자형이 결여되어 있거나, 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자가 결여되어 있거나, 둘 다 결여되어 있는 경우, 대상체는 MHC-1-병증 및/또는 MHC-1I-병증이 발병할 위험이 감소한다. 일부 구현양태에서, 방법은 대상체가 MHC-1-병증-관련 HLA 유전자형 및/또는 MHC-1I-병증-관련 HLA 유전자형의 단일 카피를 갖는지 또는 MHC-1-병증-관련 HLA 유전자형 및/또는 MHC-1I-병증-관련 HLA 유전자형의 2개의 카피를 갖는지 여부를 결정하는 것을 추가로 포함한다. 대상체가 MHC-1-병증-관련 HLA 유전자형 및/또는 MHC-1I-병증-관련 HLA 유전자형의 2개의 카피를 포함하는 경우, 대상체는 MHC-1-병증-관련 HLA 유전자형 및/또는 MHC-1I-병증-관련 HLA 유전자형의 단일 카피를 포함하는 것과 비교하여 MHC-1-병증 및/또는 MHC-1I-병증이 발생할 증가된 위험이 있다.

[0086] 일부 구현양태에서, MHC-1-병증은 BSCR이다. 일부 구현양태에서, 대상체는 HLA-Aw19⁺이다. 일부 구현양태에서, 대상체는 HLA-A29⁺, HLA-A30⁺, HLA-A31⁺, 또는 HLA-A33⁺ 또는 이들의 임의의 조합이거나 또는 그러한 것으로 의심된다. 일부 구현양태에서, 대상체는 HLA-Aw19의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-Aw19의 2개 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-A29⁺/HLA-A30⁺이다. 일부 구현양태에서, 대상체는 HLA-A29⁺/HLA-A31⁺이다. 일부 구현양태에서, 대상체는 HLA-A29⁺/HLA-A33⁺이다.

[0087] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29⁺가 아니다.

[0088] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29, HLA-A30, HLA-A31 또는 HLA-A33 중 적어도 임의의 2개의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29, HLA-A30, HLA-A31 또는 HLA-A33 중 적어도 임의의 3개의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29, HLA-A30, HLA-A31 또는 HLA-A33 모두의 하나의 카피를 갖는다.

[0089] 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A30의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A31의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A33의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A30 및 HLA-A31의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A30 및 HLA-A33의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A31 및 HLA-A33의 하나의 카피를 갖는다.

[0090] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 1개의 카피 및 HLA-A30의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 각각 HLA-A29 및 HLA-A30의 하나의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 1개의 카피 및 HLA-A33의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 1개의 카피 및 HLA-A31의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 1개 카피 및 HLA-A33의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A31의 1개의 카피 및 HLA-A33의 2개의 카피를 갖는다.

[0091] 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 2개의 카피 및 HLA-A30의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A29의 2개의 카피 및 HLA-A31의 1개의 카피를 갖는다. 일부 구현양태에서,

BSCR을 갖는 대상체는 HLA-A29의 2개의 카피 및 HLA-A33의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 2개의 카피 및 HLA-A31의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A30의 2개의 카피 및 HLA-A33의 1개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖는 대상체는 HLA-A31의 2개의 카피 및 HLA-A33의 1개의 카피를 갖는다.

[0092] 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A29의 2개 카피 및 HLA-A30의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A29의 2개 카피 및 HLA-A31의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A29의 2개 카피 및 HLA-A33의 2개 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A30의 2개 카피 및 HLA-A31의 2개 카피를 갖는다. 일부 구현양태에서, 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A30의 2개의 카피 및 HLA-A33의 2개의 카피를 갖는다. 일부 구현양태에서, BSCR을 갖거나 BSCR을 가질 것으로 의심되는 대상체는 HLA-A31의 2개 카피 및 HLA-A33의 2개 카피를 갖는다.

[0093] 일부 구현양태에서, 상기 방법은 대상체에게 HLA-Aw19 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-Aw19 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-A29 항체를 포함한다. 일부 구현양태에서, HLA-Aw19 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-Aw19에 혼성화하는 안티센스 핵산 분자, 작은 간섭 RNA(siRNA) 또는 짧은 헤어핀 RNA(shRNA)이다. 일부 구현양태에서, HLA-Aw19는 HLA-A29이다.

[0094] 일부 구현양태에서, MHC-1-병증은 AS이다. 일부 구현양태에서, 대상체는 HLA-B27⁺ 또는 HLA-B40⁺이거나 그러한 것으로 의심된다. 일부 구현양태에서, 대상체는 HLA-B27 또는 HLA-B40의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-B27 또는 HLA-B40의 2개 카피를 갖는다. 일부 구현양태에서, 상기 방법은 대상체에게 HLA-B27 억제제 또는 HLA-B40 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제 또는 HLA-B40 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-B27 항체 또는 항-HLA-B40 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제 또는 HLA-B40 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27 또는 HLA-B40에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다.

[0095] 일부 구현양태에서, MHC-1-병증은 포도막염과 결합된 건선이다. 특정 구현양태에서, 포도막염은 후방 포도막염이다. 일부 구현양태에서, 대상체는 HLA-B27이거나 그러한 것으로 의심된다. 일부 구현양태에서, 대상체는 HLA-B27의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-B27의 2개 카피를 갖는다. 일부 구현양태에서, 방법은 대상체에게 HLA-B27 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-B27 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다.

[0096] 일부 구현양태에서, MHC-1-병증은 JIA이다. 일부 구현양태에서, 대상체는 HLA-B27⁺ 및/또는 DRB1⁺이거나 그러한 것으로 의심된다. 일부 구현양태에서, 대상체는 HLA-B27 및/또는 DRB1의 단일 카피를 갖는다. 일부 구현양태에서, 대상체는 HLA-B27 및/또는 DRB1의 2개 카피를 갖는다. 일부 구현양태에서, 방법은 대상체에게 HLA-B27 억제제 및/또는 DRB1 억제제를 투여하는 것을 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제 및/또는 DRB1 억제제는 항체를 포함한다. 일부 구현양태에서, 항체는 항-HLA-B27 항체 또는 항-DRB1 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제 및/또는 DRB1 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27 및/또는 DRB1에 혼성화하는 안티센스 핵산 분자, siRNA 또는 shRNA를 포함한다.

[0097] 본원에 기재된 임의의 구현양태에서, 방법은 MHC-1-병증-관련 HLA 유전자형 및/또는 MHC-1I-병증이 발병할 위험이 증가된 대상체에게 ERAP2 억제제를 투여하는 것을 추가로 포함할 수 있다. 일부 구현양태에서, ERAP2 억제제는 소분자 분해제, 단백질분해-표적 키메라, 면역조절 약물 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 안티센스 핵산 분자, siRNA, 또는 shRNA를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 안티센스 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 siRNA를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 shRNA를 포함한다. 일부 구현양태에서, ERAP2 억제제는 항-ERAP2 항체를 포함한다. 일부 구현양태에서, ERAP2 억제제는 슈도펩티드를 포함한다. 일부 구현양태에서, 슈도펩티드는 포스포닉 슈도펩티

드이다. 일부 구현양태에서, 포스포닉 슈도펩티드는 DG002 또는 DG013이다. 일부 구현양태에서, 포스포닉 슈도펩티드는 DG002이다. 일부 구현양태에서, 포스포닉 슈도펩티드는 DG013이다. 일부 구현양태에서, ERAP2 억제제는 소분자를 포함한다.

[0098] 일부 구현양태에서, 대상체가 MHC-1-병증-관련 및/또는 MHC-1I-병증-관련 HLA 유전자형 및 기능적 ERAP2 단백질, 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 포함하는지 여부를 결정하기 위한 검정은 유전자형 검정 또는 시퀀싱 검정이다. 일부 구현양태에서, 기능적 ERAP2 단백질을 암호화하는 핵산 분자는 게놈 DNA, mRNA, 또는 mRNA로부터 수득한 cDNA를 포함한다. ERAP2 단백질 또는 핵산 분자에 대한 야생형 서열, 또는 활성이 감소되었거나 없는 변이체 ERAP2 단백질 또는 핵산 분자의 공개된 서열에 대해 대상체로부터의 샘플에서 ERAP2 단백질의 뉴클레오티드 또는 단백질 서열을 비교함으로써, 대상체가 기능적 ERAP2 단백질, 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 포함하는지 여부를 결정할 수 있다. 또한, 개별 ERAP2 단백질이 생물학적 활성을 가질 수 있지만, ERAP2 단백질의 전반적인 기능은 감소된 수준의 발현으로 인해 기능하지 않을 수 있다. 따라서, 본원에서 사용되는 바와 같이, ERAP2 단백질은 생물학적 활성이 결여되거나 감소되었기 때문에 또는 발현 수준이 감소되었기 때문에, ERAP2 단백질은 기능적이지 않은 것으로 결정될 수 있다.

[0099] 대상체가 MHC-1-병증-관련 및/또는 MHC-1I-병증-관련 HLA 유전자형 및/또는 기능적 ERAP2 단백질, 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 갖는지 여부에 대한 결정은 대상체의 생물학적 샘플에서 본원에 기술된 임의의 방법에 의해 수행될 수 있다. 일부 구현양태에서, 이들 방법은 *생체 외*에서 수행될 수 있다. 일부 구현양태에서, 이들 방법은 *체자리*(in situ)에서 수행될 수 있다. 일부 구현양태에서, 이러한 방법은 생체 내에서 수행될 수 있다. 임의의 이러한 구현양태에서, 핵산 분자는 대상체로부터 수득한 생물학적 샘플 내에 존재할 수 있다.

[0100] 생물학적 샘플은 대상체로부터의 임의의 세포, 조직 또는 생물학적 유체로부터 유래할 수 있다. 생물학적 샘플은 골수 샘플, 중앙 생검, 미세 바늘 흡입물, 또는 혈액, 치은열구액, 혈장, 혈청, 림프, 복수, 낭포액, 또는 소변과 같은 체액 샘플과 같은 임의의 임상적으로 관련 조직을 포함할 수 있다. 일부 경우에, 샘플은 협측 면봉을 포함한다. 본원에 개시된 방법에 사용되는 생물학적 샘플은 검정 형식, 검출 방법 속성, 및 샘플로서 사용된 조직, 세포, 또는 추출물에 기반하여 달라질 수 있다. 생물학적 샘플은 이용될 검정에 따라서 상이하게 가공될 수 있다. 예를 들어, 임의의 특정 핵산 분자를 검출할 때, 특정 핵산 분자에 대한 생물학적 샘플을 분리하거나 농축하도록 설계된 예비 처리가 사용될 수 있다. 다양한 기술이 이러한 목적을 위해 사용될 수 있다. mRNA 분자의 존재 또는 수준 또는 특정 게놈 DNA 유전자좌의 존재를 검출하기 위한 다양한 방법이 사용될 수 있다.

[0101] 일부 구현양태에서, 생물학적 샘플은 세포 또는 세포 용해물을 포함한다. 이러한 방법은, 예를 들어 대상체로부터 게놈 핵산 분자 또는 mRNA 분자를 포함하는 생물학적 샘플을 수득하는 것, 및 mRNA인 경우 임의로 mRNA를 cDNA로 역전사시키는 것을 포함할 수 있다. 일부 구현양태에서, 방법은 *생체 외* 방법이다. 일부 실시형태에서, 예시에는 RNA 시퀀싱(RNA-Seq)을 포함한다. 일부 실시형태에서, 검정은 또한 역전사효소 중합효소 연쇄 반응(RT-PCR)에 의한 것과 같이 cDNA로 mRNA를 역전사하는 단계를 포함한다.

[0102] 임의의 특정 HLA 대립유전자의 존재 또는 부재를 검출하는 것은 다양한 기술에 의해 수행될 수 있다. 2-자리 및 4-자리 분해능으로 HLA-A 대립유전자를 검출할 수 있다. 예를 들어, HLA 영역을 고분해능으로 표적화하는 검정법(모든 클래스 I 및 클래스 II 유전자)을 사용할 수 있다. 일부 구현양태에서, 검정은 전체 HLA 유전자(이 경우 HLA-A)를 5'UTR에서 3'UTR로 증폭하고 전체 앰플리콘(유전자의 이러한 증폭의 산물인 DNA)에 걸쳐 유전적 변이체를 제공한다. 그런 다음 방법을 사용하여 HLA-A 대립유전자를 높은 정확도로 호출할 수 있다(예를 들어, PHLAT2; Bai et al., Methods Mol. Biol., 2018, 1802, 193-201). PHLAT2의 출력은 각 샘플에 대한 HLA-A 4-자리 대립유전자 데이터를 제공하며, 이는 산탄(Birdshot) 사례에서 농축된 것으로 다른 Aw19 대립유전자를 확인하는 분석에 사용할 수 있다. 또한, HLA 유형의 상업적 공급원을 사용할 수 있다.

[0103] 기능적 ERAP2 단백질, 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자의 존재 또는 부재를 검출하는 것은 다양한 기술에 의해 수행될 수 있다. 예를 들어, ERAP2 단백질 및 관련 뉴클레오티드 서열의 존재 또는 부재의 검출은 문헌에 기재된 바와 같이 수행될 수 있다(Andres et al., PLoS Genetics, 2010, 6, 1-13). 예를 들어, rs2248374-A로 명명된 ERAP2 인트론 변이를 가진 대상체는 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 갖고 있으며 MHC-1-병증이 발생할 위험이 증가한다. rs10044354, HapA로 명명된 ERAP2 변이체를 갖는 대상체는 기능적 ERAP2 단백질, 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 가지며, MHC-1-병증이 발생할 위험이 증가한다. rs2248374-G로 명명된 ERAP2 스플라이스 변이체를 갖는 대상체는 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 가지고 있지 않으며, MHC-1-병증이 발생할

위험이 감소한다.

- [0104] 본 개시내용의 대표적인 구현양태는 다음을 포함하지만 이에 제한되지는 않는다.
- [0105] 본 개시내용은 면역 장애를 갖는 대상체를 치료하는 방법을 제공하며, 상기 방법은 ERAP2 억제제 및 i) HLA-A29 억제제 및/또는 ii) HLA-B27 억제제를 대상체에게 투여하는 것을 포함한다. 일부 구현양태에서, 면역 장애는 MHC-1-병증이다.
- [0106] 본 개시내용은 또한 MHC-1-병증을 갖는 대상체를 치료하는 방법을 제공하며, 상기 방법은 대상체가 i) HLA-A29 대립유전자 및/또는 HLA-B27 대립유전자; 및 ii) 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 포함하는지 여부를 결정하기 위해 대상체의 생물학적 샘플에 대한 검정을 수행하거나 수행했던 단계; 및 기능적 ERAP2 단백질 또는 기능적 ERAP2를 암호화하는 핵산 분자를 갖고 HLA-A29 대립유전자를 갖는 대상체에게 치료적 유효량의 ERAP2 억제제와 HLA-A29 억제제를 투여하는 단계; 또는 기능적 ERAP2 단백질 또는 기능적 ERAP2를 암호화하는 핵산 분자를 갖고 HLA-B27 대립유전자를 갖는 대상체에게 치료적 유효량의 ERAP2 억제제와 HLA-B27 억제제를 투여하는 단계를 포함하며; 유전자형 및 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자를 모두 포함하며; i) HLA-A29 대립유전자 및/또는 HLA-B27 대립유전자, 및 ii) 기능적 ERAP2 단백질 또는 기능적 ERAP2 단백질을 암호화하는 핵산 분자의 모두의 존재는 대상체가 ERAP2를 억제함으로써 MHC-1-병증을 치료하기 위한 후보임을 나타낸다.
- [0107] 본 개시내용은 또한 면역 장애의 치료에 사용하기 위한 ERAP2 억제제와 HLA-A29 억제제의 조합을 제공한다. 본 개시내용은 또한 면역 장애의 치료용 약물의 제조에 사용하기 위한 ERAP2 억제제와 HLA-A29 억제제의 조합을 제공한다. 일부 구현양태에서, 면역 장애는 MHC-1-병증이다.
- [0108] 일부 구현양태에서, MHC-1-병증은 BSCR이고, 방법은 ERAP2 억제제 및 HLA-A29 억제제를 대상체에게 투여하는 것을 포함한다. 일부 구현양태에서, 방법은 대상체로부터 수득한 생물학적 샘플에서 HLA-A29 대립유전자의 존재 또는 부재를 검출하는 것을 추가로 포함한다. 일부 구현양태에서, 방법은 대상체가 HLA-A29 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 단계를 추가로 포함한다. 일부 구현양태에서, HLA-A29 억제제는 항체를 포함한다. 일부 구현양태에서, HLA-A29 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 안티센스 핵산 분자, siRNA, 또는 HLA-A29에 혼성화하는 짧은 헤어핀 RNA를 포함한다. 일부 구현양태에서, 안티센스 핵산 분자는 서열 번호 3871 내지 4145로 구성된 군으로부터 선택되는 뉴클레오타이드 서열을 포함한다. 일부 구현양태에서, siRNA 분자는 서열번호 4146 내지 4755로 구성된 군으로부터 선택되는 센스 가닥 및 상응하는 안티센스 가닥을 포함한다.
- [0109] 일부 구현양태에서, MHC-1-병증은 AS이고, 방법은 ERAP2 억제제 및 HLA-B27 억제제를 대상체에게 투여하는 것을 포함한다. 일부 구현양태에서, 방법은 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 대립유전자의 존재 또는 부재를 검출하는 것을 추가로 포함한다. 일부 구현양태에서, 방법은 대상체가 HLA-B27 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 단계를 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제는 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, siRNA 또는 짧은 헤어핀 RNA를 포함한다. 일부 구현양태에서, 안티센스 핵산 분자는 서열 번호 2788 내지 3132로 구성된 군으로부터 선택되는 뉴클레오타이드 서열을 포함한다. 일부 구현양태에서, siRNA 분자는 서열번호 3133 내지 3870으로 구성된 군으로부터 선택되는 센스 가닥 및 상응하는 안티센스 가닥을 포함한다.
- [0110] 일부 구현양태에서, MHC-1-병증은 건선이고 상기 대상체는 포도막염을 가지고 있고, ERAP2 억제제 및 HLA-B27 억제제를 대상체에게 투여하는 것을 포함한다. 일부 구현양태에서, 포도막염은 후방 포도막염이다. 일부 구현양태에서, 방법은 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 대립유전자의 존재 또는 부재를 검출하는 것을 추가로 포함한다. 일부 구현양태에서, 방법은 대상체가 HLA-B27 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 단계를 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제는 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, siRNA 또는 짧은 헤어핀 RNA를 포함한다. 일부 구현양태에서, 안티센스 핵산 분자는 서열 번호 2788 내지 3132로 구성된 군으로부터 선택되는 뉴클레오타이드 서열을 포함한다. 일부 구현양태에서, siRNA 분자는 서열번호 3133 내지 3870으로 구성된 군으로부터 선택되는 센스 가닥 및 상응하는 안티센스 가닥을 포함한다.
- [0111] 일부 구현양태에서, MHC-1-병증은 JIA이고, 방법은 ERAP2 억제제 및 HLA-B27 억제제를 대상체에게 투여하는 것

을 포함한다. 일부 구현양태에서, 방법은 대상체로부터 수득한 생물학적 샘플에서 HLA-B27 대립유전자의 존재 또는 부재를 검출하는 것을 추가로 포함한다. 일부 구현양태에서, 방법은 대상체가 HLA-B27 대립유전자의 1개 또는 2개 카피를 가지고 있는지 여부를 결정하는 단계를 추가로 포함한다. 일부 구현양태에서, HLA-B27 억제제는 항체를 포함한다. 일부 구현양태에서, HLA-B27 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 HLA-B27에 혼성화하는 안티센스 핵산 분자, siRNA 또는 짧은 헤어핀 RNA를 포함한다. 일부 구현양태에서, 안티센스 핵산 분자는 서열 번호 2788 내지 3132로 구성된 군으로부터 선택되는 뉴클레오타이드 서열을 포함한다. 일부 구현양태에서, siRNA 분자는 서열번호 3133 내지 3870으로 구성된 군으로부터 선택되는 센스 가닥 및 상응하는 안티센스 가닥을 포함한다.

[0112] 일부 구현양태에서, ERAP2 억제제는 소분자 분해제 또는 억제성 핵산 분자를 포함한다. 일부 구현양태에서, 억제성 핵산 분자는 ERAP2 mRNA에 혼성화하는 안티센스 핵산 분자, siRNA 또는 짧은 헤어핀 RNA를 포함한다. 일부 구현양태에서, 안티센스 핵산 분자는 서열 번호 1 내지 858로 구성된 군으로부터 선택되는 뉴클레오타이드 서열을 포함한다. 일부 구현양태에서, siRNA 분자는 서열번호 859 내지 2748로 구성된 군으로부터 선택되는 센스 가닥 및 상응하는 안티센스 가닥을 포함한다. 일부 구현양태에서, ERAP2 억제제는 항-ERAP2 항체를 포함한다. 일부 구현양태에서, ERAP2 억제제는 슈도캡티드를 포함한다. 일부 구현양태에서, 슈도캡티드는 포스포닉 슈도캡티드이다. 일부 구현양태에서, 포스포닉 슈도캡티드는 DG002 또는 DG013이다. 일부 구현양태에서, ERAP2 억제제는 소분자를 포함한다.

[0113] 본 개시내용은 또한 하나 이상의 HLA-A29 억제제와 조합하여 하나 이상의 ERAP2 억제제를 포함하는 제약 조성물을 제공한다. 본 개시내용은 또한 하나 이상의 HLA-B27 억제제와 조합하여 하나 이상의 ERAP2 억제제를 포함하는 제약 조성물을 제공한다. 본 개시내용은 또한 하나 이상의 HLA-A29 억제제 및 하나 이상의 HLA-B27 억제제와 조합하여 하나 이상의 ERAP2 억제제를 포함하는 제약 조성물을 제공한다.

[0114] 본원에 개시된 요지가 보다 효율적으로 이해될 수 있도록 하기 위하여, 하기에 실시예들이 제공된다. 이러한 실시예들은 단지 예시적 목적을 위한 것이며 청구된 요지를 어떤 방식으로든 제한하는 것으로 해석되어서는 안 된다는 것을 이해해야 한다. 이들 실시예 전반에 걸쳐, 분자 클로닝 반응 및 기타 표준 재조합 DNA 기술은 달리 명시된 경우를 제외하고 상업적으로 구입가능한 시약을 사용하여 문헌에 기술된 방법에 따라 수행되었다(Maniatis et al., Molecular Cloning - A Laboratory Manual, 2nd ed., Cold Spring Harbor Press (1989)).

[0115] **실시예**

[0116] **실시예 1: 방법**

[0117] *연구 대상체 및 샘플*

[0118] 286명의 BSCR 환자와 프랑스 인구에서 공통적인 HLA 조직 유형을 나타내는 108명의 관련 없는 건강한 현지 프랑스 지원자의 게놈 DNA 샘플이 이 연구에 포함되었다. 환자들은 프랑스 파리의 코친(Cochin) 병원에서 모집되었다. 모든 환자는 2002년에 개최된 국제 합의 회의와 포도막염 명명법 표준화(SUN) 작업 그룹에서 정의한 BSCR 진단 기준을 충족했다. 간단히 말해서, 모든 환자는 다발성 크림색 또는 노란색-오렌지색, 타원형 또는 원형 맥락막 병변("산탄(birdshot) 반점")이 있는 후방 양측 포도막염을 앓았다. HLA-A29 대립유전자의 존재가 국제적 기준에 따라 BSCR의 진단을 위한 요구사항은 아니었지만, 현재 연구에 포함된 모든 환자는 HLA-A29 대립유전자를 보유하고 있었다. 대조군 DNA 샘플은 프랑스 골수 이식 등록소(France Greffe de Moelle Registry)를 위해 랭스(Rheims)의 조혈 줄기 세포 기증자 센터에 의해 모집된 지원자 기증자와 등록소의 지역 대조군 건강한 개체로부터 수집되었다. DNA 샘플은 표준 염색 방법 또는 QIAamp 혈액 키트(Qiagen, Chatsworth, CA, USA)를 사용하여 말초 혈액 샘플에서 분리되었다. DNA의 질과 양은 UV 분광광도계로 측정하였고 농도는 100 ng/ml로 조절하였다. 모든 참가자로부터 사전 동의 문서에 서명을 받았으며 모든 연구는 헬싱키 선언에 명시된 원칙을 준수했다. 모든 연구 관련 데이터 수집은 파리 코친(Paris Cochon) 기관 검토 위원회의 승인을 받았다.

[0119] *유전적 데이터*

[0120] 고품질 호출을 기반으로 필터링된 공통 및 희귀 변이체를 확인할 수 있도록 엑솜과 모든 샘플의 유전자형의 서열에 대해 포괄적인 접근 방식을 취했다. 참가자의 DNA는 일루미나 글로벌 스크리닝 어레이(Illumina Global Screening Array, GSA)에서 유전자형이 지정되었고 HRC 참조 패널에 대체되었다. 대체(imputation) 전에, MAF $\geq 0.1\%$, 누락 $< 1\%$ 및 HWE $p\text{-값} > 10^{-15}$ 를 갖는 변이체가 유지되었다. HRC 참조 패널을 사용한 대체는 대체 INFO > 0.3 및 MAF $> 0.5\%$ 로 8,385,561개의 변이체를 산출했다.

- [0121] 엑스 시퀀싱은 평균 깊이 31X로 수행되었고, 이전에 보고된 대로 변이체 호출 및 품질 관리가 수행되어(Van Hout et al., Nature, 2020, 586, 749-756) 238,942개의 변이체가 생성되었다. 통합되었을 때, 이것은 8,459,907개의 변이가 있는 전체 데이터셋을 생성했다: 65.5% 공통(MAF > 5%), 34.5% 저-빈도(0.5% < MAF < 5%) 및 0.01% 희귀(MAF < 0.5%).
- [0122] HLA 유전자형
- [0123] HLA 클래스 I 유전자(HLA-A, -B 및 -C)는 각 표적에 대한 전체 게놈 유전자좌를 포함하는 프라이머를 사용한 다중 PCR 반응에서 증폭되었다. 생성된 앰플리콘은 250 염기쌍의 평균 크기로 효소적으로 단편화되었고 일루미나(Illumina) 시퀀싱(New England Biolabs, Ipswich, MA)을 위해 준비되었다. 라이브러리는 이중 10개 염기쌍 인덱스가 있는 페어드-엔드(paired-end) 125개 염기쌍 판독을 사용하여 빠른 실행 흐름 셀의 일루미나(Illumina) HiSeq 2500 플랫폼에서 시퀀싱되었다. 시퀀싱이 완료되면, 각 일루미나(Illumina) HiSeq 실행의 원시 데이터를 로컬 버퍼 저장소에 수집하고 자동 분석을 위해 DNAnexus 플랫폼(Reid et al., BMC Bioinformatics, 2014, 15, 30)에 업로드했다. FASTQ-형식의 판독은 BCL 파일에서 변환되었으며 bcl2fastq 변환 소프트웨어(Illumina Inc., San Diego, CA)를 사용하여 특정 바코드로 확인된 샘플에 할당되었다. 샘플-특이적 FASTQ 파일의 모든 판독은 IPD-IMGT/HLA 데이터베이스 v3.30.0(Robinson et al., Hum. Immunol., 2016, 77, 233-237)에서 GRCh38 게놈 서열 및 HLA 유형 참조 서열로 구성된 참조 서열과 함께 업데이트된 버전의 PHLAT 프로그램(Bai et al., BMC Genomics, 2014, 15, 325)을 사용하여 HLA 유형 분석을 받았다.
- [0124] 또한, T1DGC HLA 대립유전자 참조 패널(Rich et al., Ann. N.Y. Acad. Sci., 2006, 1079, 1-8)을 사용하여 SNP2HLA(Jia et al., PLoS One, 2013, 8, e64683)에 따라 HLA 대립유전자 대체를 수행했다. 확장된 주요 조직 적합성 복합체(MHC) 영역(chr6:25-35Mb)에서 HRC-대체 유전자형은 T1DGC 참조 패널과의 중첩을 증가시키기 위해 높은 INFO 점수(>0.9) 및 확실성(모든 유전자형에 대해 최대 GP>0.8)에 대해 필터링되어 SHAPEIT4(Delaneau et al., Nat. Commun., 2019, 10, 5436)를 사용하여 염색체 6 어레이 유전자형과 함께 재-위상화되었고 Minimac4(Das et al., Nat. Genet., 2016, 48, 1284-1287)를 사용하여 대체되었다. HLA 대립유전자 대체 품질은 INFO 점수 대 MAF 및 대체 대 참조 패널 MAF를 조사하여 평가되었다.
- [0125] 유전적 연관성 분석
- [0126] 각 연구의 연관성 분석은 SAIGE(Mbatchou et al., bioRxiv, 2020, 2020.2006.2019.162354, doi:10.1101/2020.06.19.162354; and Zhou et al., Nat. Genet., 2018, 50, 1335-1341)에서 구현된 게놈-전체 퍼스(Firth) 로지스틱 회귀 테스트를 사용하여 수행되었다. 이 구현에서 퍼스(Firth)의 접근 방식은 표준 로지스틱 회귀 점수 테스트의 p-값이 0.05 미만일 때 적용된다. 마이너 대립유전자 빈도(MAF) >1%, <10% 누락, 하디-와인버그(Hardy-Weinberg) 평형 테스트 P -값 >10⁻¹⁵ 및 연관-비평형(LD) 전지작업(pruning)(1000개의 변이 창, 100개의 변이 슬라이딩 창 및 r^2 <0.1)를 갖는 직접 유전자형 변이체는 SAIGE용 GRM에 포함되었다. 연관 모델에는 공변량 성별 및 GRM 데이터셋에서 유래된 처음 10개의 조상-정보 주성분(PC)이 포함되었다. 일배체형 분석은 PLINK 1.0(Purcell et al., Am. J. Hum. Genet., 2007, 81, 559-575) --chap 및 --hap-assoc 및 --hap-logistic을 사용하여 그리고 R에서 수행되었다. 높은 일배체형 대체 및 단계적 품질은 PLINK에 의해 표시되었다. --hap-phase 최대 우도 일배체형 유전자형의 사후 확률은 모두 1이다.
- [0127] HLA-A 대립유전자 연관 분석
- [0128] HLA-A 대립유전자의 연관은 다음과 같이 수행되었다: 각 샘플에 대해 두 HLA-A 대립유전자는 위에서 설명한 대로 유형화되었다. HLA 대립유전자 유형 지정 후 관련 샘플이 제거되었다. 나머지 코호트의 282개 사례 및 106개 대조군의 경우, A29가 아닌 HLA-A 대립유전자("두 번째" 대립유전자) 1개를 다음으로 수득하였다. A29의 2개 카피를 포함하는 샘플은 A29를 두 번째 대립유전자로 갖는 것으로 간주되었다. 그런 다음 코호트는 3개 이상의 BSCR 사례에서 확인된 각 대립유전자와 사례-대조군 상태의 연관성을 테스트하는 피셔의 정확 테스트(Fisher's exact test)를 받았다. A19 대립유전자 군이 사례-대조군 상태와도 연관이 있는지에 대한 질문에 답하기 위해 샘플을 조합하고 두 가지 다른 방식으로 함께 테스트했다: 모든 Aw19 대립유전자(A29, A30, A31, A32 및 A33). A32는 펩티드 결합 도메인에서 다른 Aw19 대립유전자와 생물학적으로 다르기 때문에 A32를 제외한 모든 Aw19 대립유전자를 포함하는 샘플로 구성된 군도 구성하고 테스트했다. 최종 승산비와 p-값은 도 1의 표에 제시되어 있다.
- [0129] 실시예 2: HLA-Aw19 광범위한 항원 혈청형 대립유전자 및 BSCR 위험

- [0130] HLA-A29 제어 코호트는 HLA-A29와 BSCR의 강한 연관성을 제어하면서 HLA 영역을 조사할 수 있게 하여, HLA 영역에서 가능한 추가 연관 신호를 검출할 수 있게 했다.
- [0131] 첫째, HLA-A29 배경의 회귀 변이체가 BSCR 사례에서 농축되었는지 여부를 질문했다. MHC 영역 내부 또는 외부에서 회귀 단일 또는 집합 변이체의 유의미한 농축이 확인되지 않았다.
- [0132] 둘째, 질문은 HLA-A29 대립유전자 이외에 다른 HLA-A 대립유전자가 BSCR 위험을 증가시키는지 여부였다. 이 코호트에서 유형 HLA-A 대립유전자에 대한 검정(방법 참조)을 구성하고 두 번째 HLA-A 대립유전자(알려진 첫 번째 HLA-A29 이외)를 테스트하여 BSCR과의 연관성을 테스트했다. 추가 HLA-A 대립유전자는 BSCR과 연관이 있는 것으로 밝혀졌으며 가장 큰 영향을 미치는 것은 동일한 HLA-Aw19 광범위 항원 혈청형 그룹인 HLA-A29:02, A30:02, A31:01 및 A33:01에 속했다(도 1). 그룹으로서 HLA-Aw19 대립유전자는 BSCR 환자의 두 번째 대립유전자에서 상당히 농축되었다($OR=4.44$, $p=2.2e-03$, 도 2, 파란색 막대). 예를 들어, 이 결과는 HLA-A29 카피 2개를 가지고 있는 개체가 카피 1개를 가지고 있는 개체에 비해 BSCR이 발생할 위험이 더 크다는 것을 시사한다. 또한, 다른 Aw19 대립유전자가 A29와 협력하여 BSCR 공동-감수성 또는 병인에서 역할을 할 수 있음을 시사한다. HLA-Aw19 혈청형 그룹 내의 유일한 예외는 HLA-A32이며, 이는 Aw19 결합 도메인 정의를 공유하지 않는 것으로 보고된 바 있다(McKenzie et al., Genes Immun., 1999, 1, 120-129); HLA-A32는 BSCR 사례에서 고갈되어 BSCR에 대해 보호적인 것으로 보인다($OR=0.28$, $p=0.1$).
- [0133] 위의 결과는 UParis($n=108$)의 적은 수의 대조군으로 인해 두 가지 문제를 제시했다: 1) 대립유전자의 빈도는 일반 EUR 집단에서 HLA-A 대립유전자의 빈도를 나타내지 않을 수 있다. 2) 높은 OR이 여러 HLA-Aw19 대립유전자에서 복제되는 동안, 그 숫자는 중요한 연관성을 뒷받침하기에 충분하지 않다. 이러한 문제를 해결하기 위해, 가이징어 건강 시스템(Geisinger Health System)으로부터의 2개 코호트(GHS 코호트 #1, $n=77,198$ 및 GHS 코호트 #2, $n=59,072$) 및 UK 바이오뱅크(Biobank)(UKB, $n=463,315$)의 세 개의 다른 대규모 유럽(EUR) 조상 대조 집단에서 HLA-A 대립유전자의 빈도를 조사하였다. 3개 데이터세트 모두에서, 적어도 하나의 HLA-A29 대립유전자를 보유하는 EUR 샘플이 선택되어 BSCR 코호트와 일치되었다: GHS 코호트 #1의 A29 보유자 4,014명(모든 EUR 대상체의 5.2%), GHS 코호트 #2의 A29 보유자 2,829명(전체 EUR의 4.8%), 및 UKB의 A29 보유자 38,543명(전체 EUR의 8.3%). 이들 코호트에서 두 번째 HLA-A 대립유전자의 빈도를 BSCR 코호트에서 관찰된 것과 비교했다(도 2, 도 1). 결과는 HLA-A30:02(GHS 코호트 #1 $OR=4.31$, GHS 코호트 #2 $OR=6.6$, UKB $OR=4.6$) 및 HLA-A33(GHS 코호트 #1 $OR=3.4$, GHS 코호트 #2 $OR=2.8$, UKB $OR=4.9$)에 대해 가장 높은 위험 증가와 함께 BSCR 사례에서 5개의 HLA-Aw19 대립유전자 중 4개의 농축을 지지한다. 4개의 공동-감수성 대립유전자 A29, A30, A31 및 A33을 보유하는 샘플을 조합할 때, BSCR 사례에서 매우 상당한 농축이 발견되었으며, 이는 더 큰 대조군 코호트(GHS 코호트 #1 p -값 = $1.29E-06$, GHS 코호트 #2 p -값 = $1.07E-06$, UKB p -값 = $9.62E-07$, 도 1 상단 행)와 비교할 때 발견되었다. 이 분석은 이전에 보고된 바와 같이 펩티드 결합 도메인의 서열에서 생물학적 차이 때문에 A32를 제외한다. A32를 포함한 모든 Aw19 대립유전자에 대한 추가 분석은 포함되었을 때 경우의 농축이 감소됨을 보여주었다(도 1 하단 행).
- [0134] 이러한 연관성이 측정가능한 교란 요인에 의해 영향을 받는지 여부를 테스트하기 위해, 각 대조군 코호트와 비교하여 UParis BSCR 사례에서 성별 및 각 분석 세트에 대한 유전자 어레이 데이터를 기반으로 계산된 주성분이 포함된 공변량으로 HLA-A29 보유자의 두 번째 HLA-A 대립유전자의 효과를 평가하기 위해 로지스틱 회귀 테스트를 수행했다(도 3). 결과는 HLA-Aw19 공동-감수성 대립유전자인 A29, A30, A31 및 A33에 대한 위험 증가와 일치했다.
- [0135] **실시예 3: HLA-A32는 HLA-A29 양성 코호트에서 BSCR로부터 보호를 나타낸다**
- [0136] HLA-A32는 BSCR 사례(3/286, ~1%) 대 A29 보유자 대조군(4/108, 3.7%)에서 과소표시되며, 이는 위험으로부터 명목상 상당한 보호에 상응한다($OR=0.28$, $p=0.1$; 도 1). 더 큰 대조군 코호트와 비교할 때, 보호 경향은 UKB 대조군(3.4%, $OR=0.3$, $p=0.02$) 및 GHS 대조군(코호트 #1: 3.8%, $OR=0.27$, $p=0.01$; 코호트 # 2: 3.7%, $OR=0.27$, $p=0.02$) 모두에서 유지된다. 명목상 상당하지만, 이 결과는 다중 테스트 보정의 임계값을 통과하지 못하며($p=3.57e-03$) 추가 사례 코호트로 추가 검증이 필요하다.
- [0137] **실시예 4: ERAP2는 BSCR과 독립적으로 연관된다**
- [0138] 일반화 선형 혼합 모델(SAIGE)을 사용하여 성별 및 10가지 주요 구성 요소를 제어하면서 모든 변이체 및 유전자 부하를 사례-대조군 상태와의 연관성에 대해 테스트했다. 사례 및 대조군 모두 A29 대립유전자 보유자라는 사실로 인해, 예상되는 강한 HLA-A 신호는 이전 BSCR 보고서(Kuiper et al., Hum. Mol. Genet., 2014, 23, 6081-

6087)에서 125건의 사례에서 $p=6.6e-74$ 와 비교하여 가장 강한 HLA p -값 = $8.98E-07$ 에 의해 입증되는 바와 같이, 적어도 부분적으로 제어되었다. 전반적으로, 어떤 유전자좌도 게놈 전체 유의성 임계값($p < 5e-8$)을 통과하지 못했다. HLA-A의 잔여 신호 이외에 염색체 5의 *ERAP1/ERAP2-LNPEP* 유전자좌만이 $p < 1e-6$ 에서 질병과의 연관성을 보여주었다(도 2).

[0139] 이전에 보고된 이 유전자좌에서 BSCR에 대한 상위 연관성은 *ERAP2/LNPEP*, rs10044354 근처의 공통 변이체 태그이다. 이 보고된 위험 대립유전자는 강한 연관 불균형($D'=0.99$, $R^2=0.76$)에 있으며, 강한 eQTL은 *ERAP2* 발현을 증가시킨다. 결과는 산탄에 대한 위험 증가와 rs10044354의 명목상의 연관성을 보여준다($OR(95\% CI) = 1.55(1.13 - 2.11)$, $p = 5.8e-3$). 또한, rs10044354와 rs27432-rs2287987 일배체형의 상호작용에 대한 중요한 증거는 발견되지 않았다(조건부 일배체형 테스트 $p=0.46$).

[0140] 다음으로 카이퍼 등(Kuiper et al.)의 발표된 결과를 사용한 결과의 메타-분석이 수행되었고, 이는 BSCR를 갖는 *ERAP2*(rs10044354, $OR(95\% CI)=1.95(1.55-2.44)$, $p=6.2e-09$) 유전자좌에 대해 게놈-전체의 유의미한 연관성을 산출하였다(도 1). 이전 및 현재 연구 모두 201,222 bp 이상으로 분리된 *ERAP2*에 대해 일관된 방향성을 보여주었으며 현재 코호트에서 낮은 연관 불균형(LD)을 나타낸다($R^2=0.18$, $D'=0.79$).

[0141] *ERAP2*의 발현은 이전에 인트론 10의 미스-스플라이싱 및 넌센스-매개 붕괴를 통한 궁극적인 전사물 분해를 야기하는 공통 스플라이스 영역 변이체(rs2248374, $AF=0.53$)에 의해 파괴되는 것으로 보고되었고(Andres et al., PLoS Genet., 2010, 6, e1001157; and Coulombe-Huntington et al., PLoS Genet., 2009, 5, e1000766), 이는 rs10044354($R^2=0.8$, $D'=1$)로 높은 LD에 있다. 따라서, 대부분의 조상 인구의 약 25%(유럽인, $AF=0.53$; 아프리카인, $AF=0.57$ 및 남아시아인, $AF=0.58$ 포함)는 활성 *ERAP2* 단백질이 부족한 것으로 추정된다. 두 데이터세트 모두 rs2248374 연관성에 대해 조사되었으며 두 데이터세트 모두에서 명목상 유의성으로 BSCR에 대해 보호적인 것으로 나타났다(도 4). 또한, *ERAP2* 발현을 방해하는 *ERAP2*-rs2248374는 보호적이다($OR 0.56$; $95\% CI [0.45-0.70]$; $p=2.39e-07$; 도 5). 요약하면, *ERAP2* 단백질의 높은 발현은 BSCR의 위험을 증가시키고 낮은 발현은 보호적이다.

[0142] **실시예 5: BSCR 위험에 대한 HLA-Aw19 대립유전자 및 *ERAP2* 일배체형의 누적 효과**

[0143] *ERAP2* 연관 신호 사이 및 HLA-Aw19와 *ERAP2* 신호 사이의 잠재적인 상호작용은 GHS 코호트 #1로부터 286개 사례와 A29 보유자 4,014명을 사용하여 HLA-Aw19와 *ERAP2* 유전자형이 BSCR 위험에 미치는 누적 효과를 계산하여 검사했다. 먼저, 카이퍼 등(Kuiper et al.)에서 상위 비-MHC 신호인 *ERAP2*-rs10044354 위험 일배체형에 대한 분석이 단일(A29/-) 대 이중(A29/Aw19) Aw19 배경으로 계층화되어 수행되었으며, 이는 추가 *ERAP2*-rs10044354-T 변이 대립유전자, 특히 이중 A29/Aw19 배경에서 위험이 증가하는 경향을 나타내었다(도 6). rs10044354-TT와 Aw19 카피 2개와 12개 사례 및 34개 대조군의 조합이 가장 높은 위험을 갖는 것으로 밝혀졌다($OR=9.9 [4.4-21.2]$, $p=1.66e-07$, 도 7).

[0144] **실시예 6: 논의**

[0145] 새로운 대규모 BSCR 환자 코호트 및 HLA-A29 대조군의 시퀀싱은 BSCR 발병 위험 증가에 있어 *ERAP2* 다형성의 중요성을 확인했다. *ERAP2* 일배체형의 연관성은 증가된 *ERAP2* 발현이 질병 위험에 기여하는 메커니즘과 일치한다. 여러 연구에서 *ERAP2* 일배체형이 이들의 발현 및 생성된 펩티둠에 영향을 미친다고 보고했다(Kuiper et al., Hum. Mol. Genet., 2018, 27, 4333-4343; Paladini et al., Sci. Rep., 2018, 8, 10398; 및 Sanz-Bravo et al., Mol. Cell Proteomics, 2018, 17, 1564-1577).

[0146] 본 연구는 HLA-A29 위험 대립유전자 이외에 몇몇 다른 HLA-Aw19 계열 대립유전자(HLA-A29, A30, A31, A33)가 두 번째 HLA-A 대립유전자로서 추가 위험에 기여한다는 것을 발견했다. HLA-Aw19 계열 대립유전자는 유사한 항원-결합 서열을 가지므로 유사한 펩티드 모티프에 결합한다. 따라서 사례에서 Aw19 대립유전자의 농축은 BSCR에서 면역 반응의 근본적인 활성화의 추론된 메커니즘을 뒷받침한다: 이러한 대립유전자의 2개 카피를 갖는 것은 HLA-A29 양성 대조군과 비교하여 BSCR 사례에서 특정 유형의 펩티드의 세포 표면 제시를 증가시킬 수 있다. 또한, Aw19 계열 내의 HLA-A32 대립유전자가 잠재적으로 보호적이라는 것이 밝혀졌다.

[0147] HLA-A32는 대조군에 비해 BSCR 환자에서 더 낮은 비율로 발견되는 유일한 HLA-Aw19 구성원으로, 보호적일 수 있음을 시사한다. HLA-Aw19 혈청형은 처음에 관련된 계열 구성원에 결합하는 항체에 의해 확인되었다; 그러나 이것은 펩티드 결합 홈 외부의 구조를 기반으로 HLA-A 단백질을 확인한다. 세로파밀리(serofamilies)는 이후 전체 및 펩티드 결합 영역 서열에 의해 재분석되었다(McKenzie et al., Genes Immun. 1999, 1, 120-129). 펩티드 결합 영역의 서열을 비교하면 HLA-A32가 본 연구에서 새로운 위험 인자로 확인된 다른 Aw19 대립유전자인 HLA-

A29, A30, A31, A33보다 더 먼 관련이 있음이 밝혀졌다. 이러한 Aw19 대립유전자 간의 서열 차이를 조사할 때, 두 가지 주요 차이점이 분명하다: 펩티드 결합 도메인의 일부인 9번 위치 및 다른 Aw19 대립유전자는 아니고 HLA-A32에서만 발견되는 79-83번 위치의 아미노산 스트레치(도 8). 이론적으로 HLA-A32에 의해 결합된 펩티드 풀은 Aw19 계열의 나머지 구성원과 다를 것이며 반응하는 CD8 T 세포의 동일한 하위집합을 활성화하지 않을 것이다. 이것은 BSCR 포도막염 발병의 구동 요소로서 고위험 HLA-A 단백질에 제시된 구동 자가항원 펩티드 풀의 증가된 농도의 임계값 요건에 대한 가설을 뒷받침하는 추가적인 증거를 추가한다.

[0148]

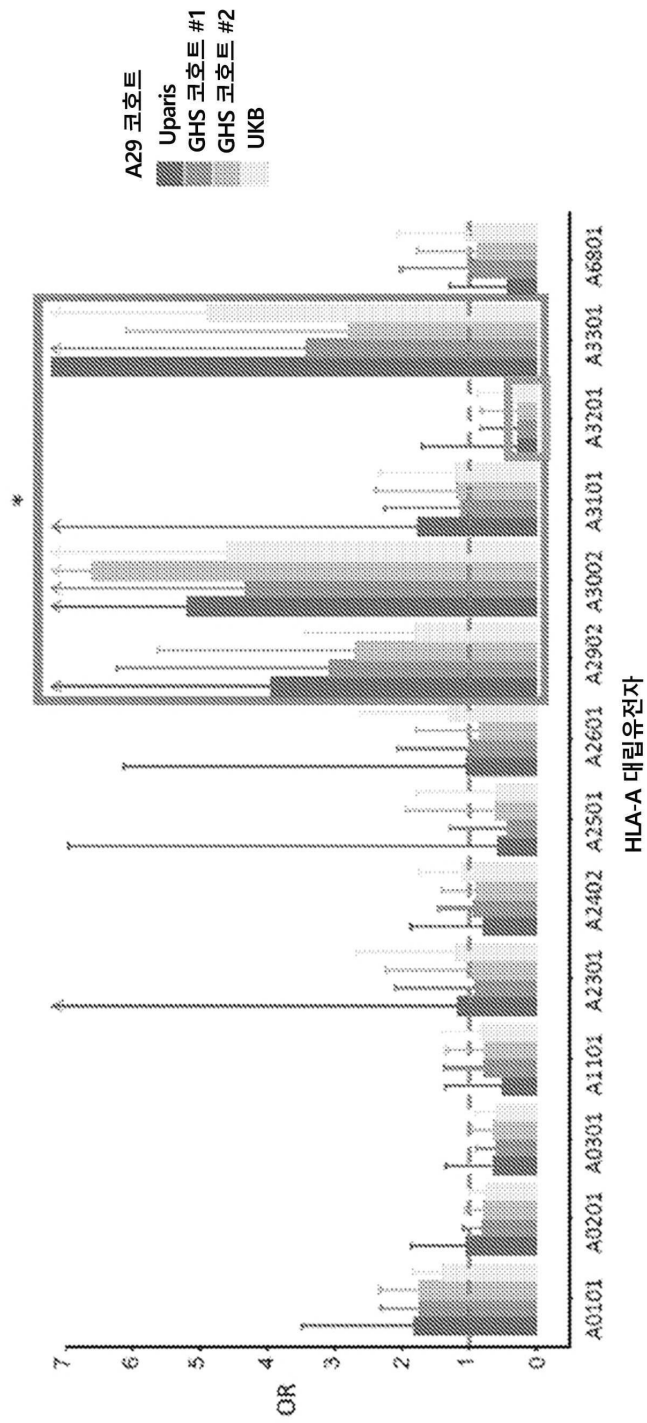
본원에 기재된 것 외에, 기재된 주제의 다양한 수정은 전술한 설명으로부터 당업자에게 명백할 것이다. 그러한 변형은 또한 첨부된 청구항의 범주 내에 속하는 것으로 의도된다. 본 출원에서 인용된 (비제한적으로, 저널 논문, 미국 및 비-미국 특허, 특허 출원 공보, 국제 특허 출원 공보, 유전자 은행 수탁 번호, 및 기타 등등) 포함하는) 각 참조는 이 전체가 참조로 본원에 편입된다.

도면

도면1

두 번째 HLA-A 대립유전자	Uparis (A29 EUR 보유자)				GHS 코호트 #1 (A29 EUR)				GHS 코호트 #2 (A29 EUR)				UKB (A29 EUR)			
	사례 수 n=286	대조군 n=108	OR (LCI-UCI)	p-값	보유자 n=4014	OR (LCI-UCI)	p-값	보유자 n=2829	OR (LCI-UCI)	p-값	보유자 n=38,543	OR (LCI-UCI)	보유자 n=38,543	OR (LCI-UCI)	p-값	
Aw19 vs. A29, A30, A31, A33	41	4	4.44 (1.55-17.50)	2.20E-03	247	2.63 (1.60-3.70)	1.25E-06	166	2.59 (1.81-3.82)	4.07E-06	2416	2.51 (1.75-3.52)	2416	2.51 (1.75-3.52)	0.025E-07	
A3402	13	1	5.19 (0.76-22.84)	0.12	45	4.31 (2.11-8.26)	6.15E-05	218	6.40 (2.98-14.13)	3.03E-06	236	4.60 (2.39-8.93)	236	4.60 (2.39-8.93)	1.25E-08	
A3301	9	0	NA (0.77-NA)	0.67	39	2.40 (1.43-2.23)	3.28E-03	32	2.50 (1.18-5.33)	0.01	255	4.50 (2.10-9.55)	255	4.50 (2.10-9.55)	1.03E-04	
A0301	26	15	0.63 (0.31-1.35)	0.20	592	0.59 (0.38-0.90)	0.01	380	0.63 (0.40-0.97)	0.03	5497	0.60 (0.38-0.90)	5497	0.60 (0.38-0.90)	0.01	
A0101	71	17	1.81 (0.99-3.48)	0.04	662	1.73 (1.29-2.31)	2.67E-04	448	1.74 (1.28-2.33)	3.21E-04	7411	1.39 (1.05-1.83)	7411	1.39 (1.05-1.83)	0.02	
A3201	3	4	0.28 (0.04-1.70)	0.19	152	0.28 (0.08-0.92)	0.01	103	0.27 (0.08-0.92)	0.02	1323	0.30 (0.09-0.86)	1323	0.30 (0.09-0.86)	0.02	
A0201	64	24	1.03 (0.59-1.85)	1.00	1085	0.80 (0.59-1.08)	0.14	756	0.78 (0.57-1.04)	0.09	10680	0.75 (0.56-1.00)	10680	0.75 (0.56-1.00)	0.05	
A2302	19	1	3.95 (0.56-27.12)	0.19	48	2.87 (1.37-6.24)	3.55E-03	27	2.70 (1.18-5.81)	9.43E-03	750	1.63 (0.80-3.43)	750	1.63 (0.80-3.43)	0.18	
A2601	8	3	1.03 (0.24-6.13)	1.00	115	1.00 (0.42-2.07)	1.00	91	0.85 (0.35-1.78)	0.86	834	1.30 (0.55-2.62)	834	1.30 (0.55-2.62)	0.41	
A2501	3	2	0.57 (0.06-6.96)	0.62	101	0.42 (0.08-1.28)	0.16	47	0.62 (0.12-1.94)	0.62	673	0.60 (0.12-1.77)	673	0.60 (0.12-1.77)	0.50	
A2402	23	11	0.79 (0.35-1.86)	0.55	356	0.92 (0.57-1.44)	0.83	249	0.89 (0.55-1.40)	0.74	2801	1.12 (0.69-1.72)	2801	1.12 (0.69-1.72)	0.57	
A3101	9	2	4.78 (0.38-19.99)	0.23	118	1.43 (0.50-2.29)	0.71	76	1.39 (0.51-2.39)	0.87	1015	1.20 (0.54-2.83)	1015	1.20 (0.54-2.83)	0.55	
A1101	14	10	0.52 (0.21-1.34)	0.16	255	0.78 (0.41-1.36)	0.44	177	0.76 (0.40-1.33)	0.44	2278	0.82 (0.44-1.40)	2278	0.82 (0.44-1.40)	0.61	
A2301	6	2	1.16 (0.20-11.91)	1.00	94	0.92 (0.33-2.10)	1.00	61	0.86 (0.34-2.24)	1.00	672	1.21 (0.44-2.68)	672	1.21 (0.44-2.68)	0.65	
A6801	9	8	0.42 (0.14-1.27)	0.09	128	1.01 (0.45-2.01)	0.86	100	0.87 (0.38-1.76)	0.87	1142	1.07 (0.48-2.06)	1142	1.07 (0.48-2.06)	0.86	
Aw19 대립유전자 (29,30,31,32,33)	44	8	2.07 (0.92-4.64)	0.08	399	1.49 (1.02-2.18)	0.04	269	1.58 (1.07-2.34)	0.02	3739	1.51 (1.04-2.18)	3739	1.51 (1.04-2.18)	0.03	

도면2



도면3

두 번째 HLA-A 대립유전자	Uparis (A29 EUR 보유자)			GHS 코호트 #1 (A29 EUR)			GHS 코호트 #2 (A29 EUR)			UKB (A29 EUR)		
	사례 n=286	대조군 n=108	p-값	보유자 n=4014	OR (LCI- UCI)	p-값	보유자 n=2829	OR (LCI- UCI)	p-값	보유자 n=38,543	OR (LCI- UCI)	p-값
A*01:01 {29,30,31,33}	41	4	0.01	247	2.21 (1.47- 3.33)	1.66E- 04	104	2.49 (1.83- 3.31)	2.34E- 06	2416	2.24 (1.82- 3.30)	4.57E- 05
A*02:01	13	1	0.16	45	2.78 (1.31- 5.88)	7.65E- 03	20	4.28 (1.83- 9.92)	7.65E- 04	366	4.91 (2.55- 7.84)	4.99E- 05
A*03:01	9	0	0.96	39	3.12 (1.28- 7.68)	0.01	32	2.69 (1.18- 6.28)	0.02	265	2.09 (0.80- 5.01)	0.14
A*03:01	26	15	0.35	592	0.69 (0.45- 1.08)	0.11	380	0.72 (0.46- 1.14)	0.16	5497	0.65 (0.43- 1.01)	0.05
A*01:01	71	17	0.05	662	1.57 (1.15- 2.16)	0.00	448	1.59 (1.15- 2.19)	0.01	7411	1.82 (1.35- 2.45)	0.00
A*02:01	3	4	0.96	152	0.30 (0.09- 0.97)	4.38E- 02	106	0.22 (0.08- 0.53)	2.62E- 02	1523	0.28 (0.08- 0.99)	3.53E- 02
A*02:01	64	24	0.92	1085	0.87 (0.64- 1.20)	0.41	756	0.87 (0.63- 1.20)	0.41	10680	0.82 (0.61- 1.11)	0.20
A*29:02	13	1	0.27	48	1.83 (0.80- 4.29)	0.15	37	1.84 (0.84- 4.06)	0.12	760	2.19 (1.05- 4.23)	0.04
A*26:01	8	3	0.90	115	0.87 (0.39- 1.91)	0.72	91	0.91 (0.40- 2.09)	0.82	834	0.73 (0.33- 1.61)	0.44
A*25:01	3	2	0.54	101	0.57 (0.16- 2.01)	0.38	47	0.69 (0.18- 2.62)	0.59	673	0.66 (0.20- 2.15)	0.49
A*24:02	23	11	0.67	356	0.99 (0.61- 1.61)	0.97	249	1.06 (0.65- 1.74)	0.81	2801	1.00 (0.63- 1.59)	0.99
A*31:01	9	2	0.48	115	1.42 (0.68- 2.97)	0.36	76	1.57 (0.72- 3.41)	0.26	1046	1.24 (0.58- 2.64)	0.67
A*11:01	14	10	0.19	255	0.81 (0.45- 1.48)	0.50	177	0.83 (0.45- 1.53)	0.54	2278	0.82 (0.46- 1.45)	0.49
A*23:01	6	2	0.94	94	0.85 (0.34- 2.17)	0.74	61	0.73 (0.28- 1.95)	0.53	672	0.85 (0.35- 2.10)	0.73
A*68:01	9	8	0.09	128	0.95 (0.45- 2.04)	0.90	100	0.76 (0.35- 1.67)	0.50	1142	1.43 (0.70- 2.91)	0.33
A*19 대립유전자 {29,30,31,32,33}	44	8	0.00	399	1.49 (1.02- 2.18)	0.04	298	1.58 (1.07- 2.34)	0.02	3738	1.51 (1.04- 2.18)	0.03

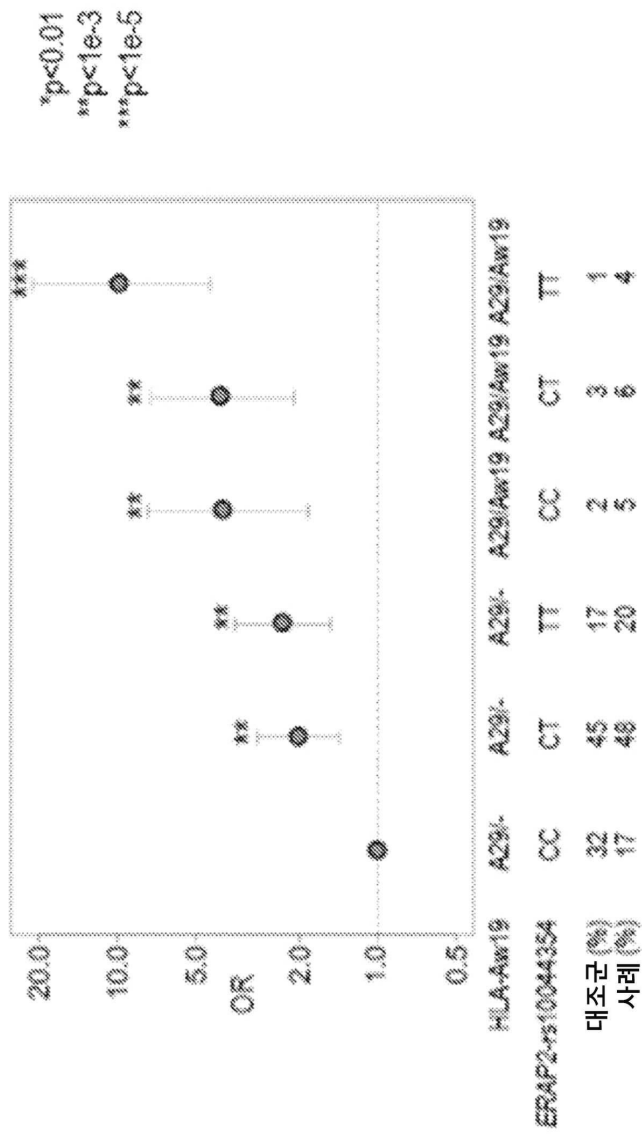
도면4

유전자	변이	변이형	조사	OR (LCI-UCI)	p-값	Hom OR	사례 MAF	대조군 MAF	메타 OR (LCI-UCI)	메타 p-값
ERAP2- LNPEP	rs10044354 5:96984791:C:T	인트론	Kuiper et al.	2.3 (1.69- 3.61)	1.21E- 06		0.63	0.42	1.95 (1.55- 2.44)	6.20E- 09
			UParis	1.55 (1.13- 2.11)	5.80E- 03	2.6 (1.3- 5.15)	0.52	0.41		

도면5

유전자	변이	변이형	조사	OR (LCI- UCI)	p-값	Hom OR	사례 MAF	대조군 MAF	메타 OR (LCI-UCI)	메타 p-값
ERAP2	rs2248374 5:96900192:A:G	스플라이스 영역	Kuiper et al.	0.44 (0.31- 0.63)	6.60E- 06		0.33	0.53	0.56 (0.45- 0.70)	2.39E- 07
			UParis	0.68 (0.5- 0.92)	1.40E- 02	0.45 (0.23- 0.87)	0.43	0.53		

도면6



도면7

Aw19	ERAP2- rs10044354	사례_n	대조군_n	사례_F	대조군F	OR	OR CI_낮음	OR CI_높음	P
A29/-	CC	46	1296	0.167	0.319	1.000	NA	NA	NA
A29/-	CT	132	1842	0.478	0.453	2.019	1.421	2.911	3.95E-05
A29/-	TT	56	681	0.203	0.167	2.316	1.522	3.539	4.51E-05
A29/Aw19	CC	13	94	0.047	0.023	3.891	1.861	7.644	2.13E-04
A29/Aw19	CT	17	119	0.062	0.029	4.019	2.092	7.413	2.32E-05
A29/Aw19	TT	12	34	0.043	0.008	9.902	4.378	21.197	1.16E-07

도면8

대립유전자/위치	9	17	56	62	63	70	73	76	77	79	80	81	82	83	97	105	109	114	116	152
A*01:01:01:01	F	R	G	Q	E	H	T	A	N	G	T	L	R	G	I	P	F	R	D	A
A*29:02:01:01	T	-	-	L	Q	Q	-	-	-	-	-	-	-	-	M	S	-	-	-	V
A*30:02:01:01	S	S	R	-	-	-	-	E	-	-	-	-	-	-	-	S	-	E	H	R
A*31:01:02:01	T	-	R	-	-	-	I	V	D	-	-	-	-	-	M	S	-	Q	-	V
A*32:01:01:01	-	-	-	-	-	-	-	E	S	R	I	A	L	R	M	-	L	Q	-	V
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Ex2

Ex3

서 열 목 록

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Baras, Aris

Moscati i, Arden

Stahl, Ali A.

Kosmicki, Jack A.

Ferreira, Manuel Alan Revez

Romano, Carmelo

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