

the correlation with and sensitivity in predicting the risk of developing sulfasalazine induced severe skin adverse reactions (SCAR) (SCAR vs. healthy control group: $P=2.67 \times 10^{-7}$, odds ratio=7.1 (3.0-16.9), sensitivity: 75.00%, specificity: 60.35%).

Based on the above results, the presence of HLA-B*1301 allele, HLA-B*1502 allele, HLA-B*3802 allele, HLA-B*3901 allele, a HLA-B*1301 allele and HLA-B*3901 allele combination, a HLA-B*1502 allele and HLA-B*3802 allele combination, a HLA-B*1301 allele, HLA-B*3802 allele and HLA-B*3901 allele combination or a HLA-B*1301 allele, HLA-B*1502 allele, HLA-B*3802 allele and HLA-B*3901 allele combination can be used to assess the risk of developing adverse cutaneous drug reactions caused by the anti epileptic drug lamotrigine disease-modifying antirheumatic drugs.

Table 1. Analysis and Comparison of the HLA-B*1301 and/or HLA-B*1502 and/or HLA-B*3802 and/or HLA-B*3901 genotype in 32 patients with severe cutaneous adverse drug reaction induced by the disease-modifying antirheumatic drug, sulfasalazine and 755 normal healthy controls.

HLA-B and SCAR	SCAR I (%)	Health Control N (%)	Odds		P value	Sensitivity	Specificity
			Ratio			(%)	(%)
			(95% CI)				
<i>HLA-B*13:01</i>							
Sulfasalazine-	1/11	114/941	0.7	(0.1	1	9.09	87.89
SJS/TEN	(9.09%)	(12.11%	to 5.7)				
		)					

Claims

1. A method for assessing the risk of developing a severe cutaneous adverse drug reaction (SCAR) in a patient, comprising the step of detecting the presence of at least one allele selected from the following:

(a) ~~HLA-B*1502 allele;~~

(~~b~~a) HLA-B*3802 allele; ~~or~~

(~~e~~b) a combination of HLA-B*1301 allele and HLA-B*3901 allele, or

(c) any combination thereof

wherein the presence of ~~at least one the~~ HLA allele selected from (a), (b) or (c) indicates the patient has a higher risk of developing the severe cutaneous adverse drug reaction induced by ~~sulfasalazine a disease-modifying antirheumatic drug~~ compared to a patient without the corresponding HLA allele.

2. The method according to claim 1, wherein said severe cutaneous adverse drug reaction comprises at least one adverse reaction selected from the following: Stevens Johnsons Syndrome (SJS), toxic epidermal necrolysis (TEN) or drug rash with eosinophilia and systemic symptoms (DRESS).

3. The method according to claim 1, further comprising detecting HLA-B*1502 allele in combination with HLA-B*3802 allele.

~~34.~~ The method according to claim 1 or 3, wherein said HLA-B*1502 allele, HLA-B*3802 allele, ~~or a combination of HLA-B*1301 allele and~~ or HLA-B*3901 allele ~~are~~ is

detected in the DNA, RNA, proteins, cells or serum sample prepared from the peripheral blood of the patient.

~~4. The method according to claim 1, wherein said disease-modifying antirheumatic drug is Sulfasalazine, Mesalazine, Sulfapyridine or Olsalazine.~~

~~5. A detection kit for assessing the risk of developing cutaneous drug adverse reactions induced by disease-modifying antirheumatic drugs in a patient, said kit comprises a reagent for detecting the presence of at least one allele selected from the following:~~

~~(a) HLA-B*1502 allele;~~

~~(b) HLA-B*3802 allele; or~~

~~(c) a combination of HLA-B*1301 allele and HLA-B*3901 allele.~~

~~6. The detection kit according to claim 5, wherein said severe cutaneous adverse drug reaction comprises at least one adverse reaction selected from the following: Stevens Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN) or drug rash with eosinophilia and systemic symptoms (DRESS).~~

~~7. The detection kit according to claim 5, said kit comprises an oligonucleotide that specifically hybridizes to the nucleic acids of the HLA allele.~~

~~8. The detection kit according to claim 5, wherein said disease-modifying antirheumatic drug is Sulfasalazine, Mesalazine, Sulfapyridine or Olsalazine.~~

~~95.~~ The use of a reagent for detecting ~~HLA-B*1502 allele, HLA-B*3802 allele, or a~~
combination of HLA-B*3901 allele and HLA-B*1301 allele or any combination
thereof ~~and~~ in the manufacture of a detection kit to evaluate the risk of developing
severe cutaneous adverse drug reactions induced by sulfasalazine ~~disease-modifying~~
~~antirheumatic drugs.~~

~~106.~~ The use according to claim 95, wherein said severe cutaneous adverse drug
reaction comprises at least one adverse reaction selected from the following: Stevens
Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN) or drug rash with
eosinophilia and systemic symptoms (DRESS).

7. The use according to claim 5, further comprising a reagent for detecting HLA-
B*1502 allele in combination with a reagent for detecting HLA-B*3802 allele.

~~118.~~ The use according to claim 95 or 7, wherein said kit comprises an oligonucleotide
that specifically hybridizes to the nucleic acids of the HLA allele.

~~12.~~ The use according to claim 9, wherein said ~~disease-modifying antirheumatic drug~~
~~is Sulfasalazine, Mesalazine, Sulfapyridine or Olsalazine.~~