Non-invasive testing to aid in the diagnosis of allergies using fingermark depositions

Published: 21-03-2014
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The goal of this study is developing a non-invasive method to test for a specfic allergy using fingermarks.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON45058

Source
ToetsingOnline

Brief title
Allergy diagnosis using fingermarks

Condition

- Allergic conditions

Synonym
allergy, hypersensitive

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: allergens, allergy, fingermarks, non-invasive test

Outcome measures

Primary outcome

Positive reaction after the skin prick test, whereby a drop of a solution containing the allergen is placed on the skin, next to this a serie of needle pricks allows the solution to enter the skin, resulting in a red, raised itchy area (called a wheal). Positive staining after incubation of a specific allergen in the fingermark.
Negative reaction after injection of a specific allergen after the skin prick test. Negative staining after incuabation of a specific allergen in the fingermark (no staining).

Determination of specific allergies in as well the intracutaneous skin prick test as the fingermark.

Saliva will be used as control --> Increased or no increased level of total IgE

Secondary outcome

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Study description

Background summary

Allergic reactions are caused by the natural defense system of the human body that fights against harmless substances (allergens) present in the environment (food, air etc). This reaction can cause symptoms, like a rash, running nose and itchy eyes. To determine whether an individual is allergic to a specific allergen, several tests are available, such as a skin prick test or blood analyses. In most cases, these test are invasive and are recorded as painful to the patient.
In this study a non-invasive method is tested. Instead of a skin-prick-test, the allergens are incubated on fingermarks. It is known that antibodies specific to an allergen are excreted in human sweat. Fingermarks are composed of natural secretions, excreted via the pores to the surface of the skin. We hypothesized that antibodies specific for an allergen are present in the fingermark depositions.
Fingermarks are placed by the volunteers on a glass slide or nitrocellulose membrane. The fingermarks are incubated with an allergen conjugated to a visual enhancer. If the antibody specific to that particular allergen is present, a positive staining will occur. Besides, placing the fingermarks, also a skin prick test will be performed. The two test results will be compared, leading to a conclusion, whether fingermarks can be used as non-invasive allergy test. Saliva will be used as a controle, the presence of total IgE will be investigated.
If fingermarks can be used as non-invasive method for allergy testing, it will be of a major impact to the allergy diagnostics.

Study objective

The goal of this study is developing a non-invasive method to test for a specfic allergy using fingermarks.

Study design

Observational study.

Study burden and risks

The nature of the burden is classified as minimal, considering that subjects have to undergo the skin prick test and have to come to the Academic Medical center for one session. The risks involved are negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- rhiniconjunctivitis +/- asthma
- allergic symptoms, provocation after contact with trees, grass, mites, dogs and/or cats.
- positieve skin pricktest for specific allergen in consistency with symptoms
-18 years and older.
- mentally competent
- no comorbidity which interferes with the skin prick test;control subject:
- no rhinoconjunctivitis, asthma of eczema
- 18 years or older
- mentally competent
- no comorbidity
- negative skinpricktest

Exclusion criteria

- younger than 18 years

- not mentally competent
- comorbidity, which interferes with the skinprick test
-negative skin prick test

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	21-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL44936.018.13