Clinical validation of the NOVEOS immunoassay for allergy diagnostics

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

Summary

ID

NL-OMON51863

Source
ToetsingOnline

Brief title
Clinical validation of the NOVEOS immunoassay

Condition

- Allergic conditions

Synonym
Allergy, hypersensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Ministerie van OC&W,Firma Sysmex

Intervention

Keyword: Allergy, Diagnostics, IgE, Immunology

Outcome measures

Primary outcome

sIgE against 12 allergens is determined on the NOVEOS system and compared with the results of the skin prick tests, the clinical diagnosis and sIgE measurements on the standard method (Siemens Immulite).

Secondary outcome

There will be investigated whether the use of biotin supplements leads to different results on the NOVEOS compared to the Immulite.

In addition, it will be investigated whether there is less interference of sIgE against CCDs on the NOVEOS.

Study description

Background summary

Allergies are caused by an immunological reaction in which specific IgE (sIgE) antibodies are formed against certain allergens. Recently a new system has become available for measuring sIgE; the *NOVEOS Immunoanalyzer*. In this system, only 4 µl of patient serum is needed to measure sIgE against an allergen. Because this is about 10% of the amount of serum needed for the systems currently in use, it is possible to measure sIgE against more allergens with less patient material (for example in children). In addition, the NOVEOS system is designed in such a way that there is no interference with biotin in serum and sIgE against CCDs (so-called Cross-reactive carbohydrate determinants), which will potentially lower the number of false negative and false positive test results, respectively. With the NOVEOS sIgE can be measured against various allergen components and allergen extracts.
The Department of Medical Immunology of the RHMDC, in collaboration with the Delft Allergy Center in the RDGG, will perform a clinical validation on the NOVEOS system.

Study objective

The aim is to evaluate the clinical performance of the system and verify the claims of reduced interference with biotin and CCDs. The measurements on NOVEOS will be mirrored in this study against the clinical diagnosis, the outcome of skin prick tests and compared to the performance of the Siemens Immulite that is currently in use for measuring sIgE. The focus in this study will be on food allergens.

Study design

In all patients, a specific combination of sIgE against allergens in serum will be measured on the NOVEOS system and on the Siemens Immulite. To determine whether sIgE against these allergens also leads to a clinically relevant allergy and to explain discrepancies between the NOVEOS and Immulite, a skin prick test will also be performed in these patients. For the NOVEOS system, clinical specificity, sensitivity and correlation will be determined.

Study burden and risks

Patients are asked to donate a tube of clot blood once and to take a skin prick test.

Contacts

Public
Reinier de Graaf Groep

Reinier de Graafweg 7
Delft 2625 AD
NL
Scientific
Reinier de Graaf Groep

Reinier de Graafweg 7
Delft 2625 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Age > 3 years
Suspected food allergy to peanut, cow's milk, chicken egg, nuts, sesame seeds, cod and/or wheat.

Exclusion criteria

Use of anti-IgE injections (Xolair), systemic corticosteroids, or anti-histamines (which should be discontinued three days before performing a skin prik test).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-06-2022
Enrollment:	326
Type:	Anticipated

Medical products/devices used

Generic name:	NOVEOS analyzer
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-06-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL80255.058.22