A Multicenter Clinical Evaluation Study to Determine the External Site Accuracy of Total Immunoglobulin E Measurement using a Novel Point-of-Care Test Device Compared to a Reference Method in Atopic Subjects

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON44019

Source
ToetsingOnline

Brief title
DIGE0012201

Condition

- Bronchial disorders (excl neoplasms)

Synonym
allergic asthma, atopic asthma

Research involving

Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma B.V. (opdrachtgever/sponsor van dit onderzoek)

Intervention

Keyword: Accuracy, Atopic Subjects, Point-of-Care Test Device, Total IgE

Outcome measures

Primary outcome

Primary endpoints:

* Total IgE concentration in capillary blood measured with the POCT device.

* Total IgE concentration in venous blood measured with the reference method.

Secondary outcome

Secondary endpoints:

* Device usability questionnaire.

Study description

Background summary

In asthma, increased serum IgE levels are associated with moderate-to-severe disease and often represent difficult-to-treat cases. Serum total IgE levels are measured as part of the clinical assessment of this patient population to determine the best treatment option for individuals.

Novartis Pharmaceuticals has developed a new method with a new device for measuring the total amount of IgE in the blood. The new method involves testing a drop of blood on an office-based instrument that will give results within a few minutes of taking the blood sample. Once approved, this new method of measurement will allow the diagnosis and treatment of patients with allergic conditions to be made sooner than with current laboratory tests.

Study objective

The purpose of this study is to determine the accuracy of the point-of-care IgE assay in atopic patients and healthy subjects. The POCT results will be compared to a reference immunoassay method for measuring this analyte.

It intends to use this new method in everyday practice making diagnosis faster, easier, less stressful, moreover (fingerstick versus venapuncture), resulting in improved clinical treatment of atopic patients.

Study design

This multi-centre study will enroll approximately 120 patients with atopic conditions and approximately 40 healthy subjects (In Netherlands 30 adult atopic patients). Subjects enrolled in this study will not receive any study medication nor have any change in their current treatment as a result of their participation.

Subjects will attend for a screening visit (visit 1) and, if eligible to be enrolled, for a blood sampling visit (visit 2).
At the blood sampling visit (Visit 2), all subjects will have two fingerprick samples of blood tested using the POCT device and two venous blood samples collected. One venous blood sample will be shipped to the reference laboratory, and the other venous blood sample will be stored as plasma (a) in case repeat testing of total IgE concentration is required, and (b) to be used in the development of future total IgE and other related assays.

Intervention

Study duration: 1-2 weeks. 2 visits of approximately 1 hour.
Blood Collection (venapunction): 2x, about 11 ml each time.
Finger prick: 2x

Study burden and risks

The risks associated with taking part in this study are possible side effects due to taking blood samples.
The risks of taking blood samples may include fainting, pain and/or bruising. Rarely, there may be a small blood clot or infection where the needle punctures the skin.
The finger prick testing may result in bruising or risk of infection in the fingertip.

Contacts

Public
Novartis

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria for patients:
1. Male or female subjects who are aged *18 years.
2. Subjects who are diagnosed with atopic asthma or other atopic condition for a minimum of 6 months prior to study entry. There should be documented evidence of sensitization to one or more specific allergens.;Inclusion criteria for healthy volunteers: N/A for the Netherlands. Besides, adults only (minimum age of 18) will be included in the Netherlands.

Exclusion criteria

Exclusion criteria for patients:
1. Subjects who have received treatment with omalizumab or other anti-IgE antibody

treatment in the past 6 months.
2. Subjects who have elevated serum IgE levels for reasons other than allergic conditions (e.g., parasite infections, hyperimmunoglobulin E syndrome, Wiskott-Aldrich syndrome, or bronchopulmonary aspergillosis).;Exclusion criteria for healthy volunteers: N/A for the Netherlands.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	13-05-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-01-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	03-03-2016
Application type:	Amendment

Review commission: METC Brabant (Tilburg)

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	NL52478.028.15