Improved laboratory diagnostics for hypersensitivity reactions

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

Summary

ID

NL-OMON57288

Source
ToetsingOnline

Brief title
IMPROVE-HR

Condition

- Allergic conditions

Synonym
allergy, Hypersensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diagnostic test, hypersensitivity, IgE, T-cells

Outcome measures

Primary outcome

1) An optimized in vitro test to diagnose the culprit of the type 1 allergy, particularly allergens for which no commercial tests with sufficient sensitivity are available and/or to replace (oral) challenge of the patient.

2) An optimized in vitro test to diagnose the culprit of the type 4 allergy, particularly allergens that cannot be used to challenge the patient due to fear of recurrence of severe allergic reactions.

3) In vitro tests with sufficient sensitivity that can (partly) replace time and recourse consuming in vivo tests.

Secondary outcome

NA

Study description

Background summary

Allergy is on the rise worldwide leading to an increase in patients referred to a specialist, and growing waiting lists. The current gold standard for diagnosis is the in vivo test. In vivo tests have as down side that they are very time consuming and can pertain a certain risk to the patient as they are re-exposed to a potential, severe allergen. This can lead to (temporary) discomfort, but theoretically also to life-threatening recurrence of the allergic reaction. In vitro testing, using laboratory assays, would circumvent these risks and make diagnostics more readily available in current times of growing numbers of allergic patients.

Study objective

Current laboratory tests for hypersensitivity are not sensitive of do not exist for certain allergens omong which medical drugs. To objective is therefore to optimize existing in vitro tests (lymphocyte activation and proliferation test, cytokine production tests and (indirect) basophil activation test (BAT) to diagnose type 1 and type 4 hypersensitivity with high sensitivity and specificity.

Study design

Prospective test comparison study

Study burden and risks

Subjects participating in the study will not experience any delay, disadvantage in their medical care nor miss any regular treatment. Vena puncture to draw blood may result in a temporary hematoma at the site of puncture. The results of this study will have no direct impact on the patient*s treatment. However, it is important to remember that the knowledge gained may have an impact on our future practice in the diagnosis of allergic diseases.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Patients with (suspected) hypersensitivity (type 1 or type 4)
o Patients with proven hypersensitivity (type 1 of type 4) will be included for development of the assays
o Patients with suspected hypersensitivity (type 1 of type 4) will be included for validation purposes
• Age >=18
• Informed consent given

Exclusion criteria

• No informed consent
• Insufficient knowledge of Dutch or English language and/or inability to understand the
information provided.
• Systemic immune suppressive treatment for the past 2 months

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):	01-12-2024
Enrollment:	100

Type:	Anticipated

Ethics review

Approved WMO Date:	27-01-2025
Application type:	First submission
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	NL86689.018.24