Blood immune analysis for precision diagnosis of medication allergy

Published: 29-10-2024
Last updated: 22-12-2024

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

Summary

ID

NL-OMON57077

Source
ToetsingOnline

Brief title
Immune monitoring of medication allergy

Condition

- Allergic conditions

Synonym
Medication allergy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: blood test, medication allergy, sensitization, type I hypersensitivity

Outcome measures

Primary outcome

The main study parameter is the detection of allergen-specific IgE, either soluble in plasma or on the cell surface of immune cells. Allergic sensitization will be defined as detection of IgE concentrations above the 95th percentile of that detected in unaffected controls

Secondary outcome

NA

Study description

Background summary

Allergic responses to medication can be life-threatening and require future avoidance. As this can involve important, common drugs, such as antibiotics, Nonsteroidal anti-inflammatory drugs (NSAIDs), and contrast material for radiology images, this posed an increasing challenge in health care. Importantly, less than 10% of reported adverse events constitute a true allergic response, and the majority of patients with a presumed allergy unnecessarily avoid medications. This is due to a lack of precision diagnostics for drug allergy sensitization that does not require a challenge test.

Study objective

The primary objective of this study is to determine if medication allergy sensitization can be accurately determined through a laboratory test with a patients* blood sample. The secondary objective is to develop a laboratory assay that can be applied to perform differential diagnosis, e.g. to investigate cross-allergy between multiple beta-lactam antibiotics to inform whether the patients can tolerate one class or has to avoid all.

Study design

This is an observations study into which adults are recruited with a proven allergic response to medication, such as antibiotics, contrast reagents, anesthetics, NSAIDs, lidocaine, biologicals and peri-operative drugs. All recruits will be asked to donate 50mL of venous blood for laboratory analysis. In addition, they will be asked to share basic demographics (age, sex, medical history); details of allergic responses and current medication use will be obtained from their medical records.

Study burden and risks

There is no perceived risk to the participants, investigators or institution. Participants are having an additional 50 mL of blood sample taken along with routine care. All blood sampling will follow Good Clinical Practice.
This research will not provide a direct therapeutic benefit to the participant, as they will continue to receive standard treatment of care. However, we hope it will contribute to improving treatment and monitoring of allergy in the future.
This research will aid in identifying potential biomarkers of allergy and its treatment. This will have positive impacts in the field of Allergy by potentially improving patient diagnosis and treatment.

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

- Aged 18 years or older
- Have recently been diagnosed with a type I medication allergy
- Provided written informed consent

Exclusion criteria

- Under systemic immunosuppressive treatment
- History of hematological malignancy, immunodeficiency or autoimmune disease
- Active infection

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	400
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	29-10-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL87449.078.24