Blood immune analysis to predict severity and threshold of the allergic response in children

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

Primary: Evaluate whether quantification of functional IgE on basophils of food allergic patients can omit the need for food challenge tests to diagnose severity and threshold of the allergic reaction. Secondary: Evaluate whether numbers of...

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

Summary

ID

NL-OMON57078

Source
ToetsingOnline

Brief title
Immune monitoring of food allergy in children

Condition

- Allergic conditions

Synonym
food 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, food allergy, pediatrics, sensitization

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

Food allergies are a major health concern with about 6-8% of children Western countries affected. Food allergies are associated with a risk of severe reactions (anaphylaxis) to common ingredients (peanut, cow*s milk, egg and nuts), having a great impact on quality of life of children and their families. There is a lack of practicable precision diagnostics, and therefore children need to undergo an oral food challenge test, which has a risk of severe reactions.

Study objective

Primary: Evaluate whether quantification of functional IgE on basophils of food allergic patients can omit the need for food challenge tests to diagnose severity and threshold of the allergic reaction. Secondary: Evaluate whether numbers of immunophenotypes of allergen-specific B- and T-cells predict the severity and/or threshold of the allergic reaction.

Study design

This is an observations study into which children (2-18 yr) are recruited with a diagnosis of allergy. All recruits will be asked to donate 9-18mL of venous

blood for laboratory analysis. In addition, they will be asked to share basic demographics (age, sex); 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 9-18 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. However, we hope it will contribute by improving diagnosis, monitoring and treatment of allergies in the future. The project will aid in identifying potential biomarkers of allergy and treatment options. This project 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

Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Aged 2-18 years
- 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
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	360
Type:	Anticipated

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	NL86818.078.24