Analysis of the potency of individual allergens in relation to IgE recognition in patients with cow's milk, peanut or nut allergy.

Published: 12-07-2011 Last updated: 29-04-2024

To analyse which allergens within cow's milk, peanut or nuts are most potent in activation of T cells and basophils.

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

Summary

ID

NL-OMON36035

Source ToetsingOnline

Brief title Role of individual allergens in food allergy.

Condition

• Allergic conditions

Synonym food allergy, food hypersensitivity

Research involving Human

Sponsors and support

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

1 - Analysis of the potency of individual allergens in relation to IgE recognition i \dots 14-05-2025

Intervention

Keyword: basophil, food allergy, IgE, T cell

Outcome measures

Primary outcome

- * T cell activation: which allergen is the most potent T cell activor?
- * Basophil activation test: which allergen is the most potent basophil

activator?

Secondary outcome

not applicable

Study description

Background summary

The prevalence of food allergy is estimated around 2% in adults and 5-8% in children. Symptoms of a food allergic reaction can vary from mild (itching in the oral cavity) to severe (anaphylactic shock). Most foods contain several allergens. IgE of patients is often directed against several allergens. It is known that not all allergens are equally important for the clinical allergic reaction. The severity of the symptoms can also differ, depending on the allergen which is involved.

Little is known about the factors that determine the relevance of an allergen for the allergic reaction. A possible explanation may be the stability of allergens, the number of IgE epitopes recognized within an allergen, or intrinsic features of the allergen, which influence the extent of mast cell and T cell activation by allergens. For many food allergens, it is unclear what these factors are and which allergens are most relevant. Insight into the in vitro characteristics of the different allergens can provide important information to determine whether IgE recognition of these specific allergens is relevant for the diagnosis of food allergy.

Study objective

To analyse which allergens within cow's milk, peanut or nuts are most potent in activation of T cells and basophils.

Study design

Because our research in recent years has focussed on cow's milk, peanut and nut allergy, we will include patients with these food allergies in this study. For each allergen (cow's milk, peanut, nut) 30 patients will be included and asked to donate blood. Because the tests for basophil activation and T cell activation cost larger amounts of blood, we will ask to donate 2 x 100 ml blood, with at least one month in between.

From the first blood sample, plasma will be collected and will be used to measure IgE binding to the individual allergens by immunoblot. This will provide information about the extent of recognition of the allergens by IgE. The white blood cells (PBMCs) will be used to analyse the potency of allergens to activate T cells. For this purpose, allergen-specific T cell lines will be generated from PBMCs. Activation of T cells is measured by proliferation and cytokine production upon allergen-specific stimulation.

The other blood sample will be used for analysis of basophil activation, to measure how potent individual allergens are to activate basophils. Basophils will be stimulated with an increasing allergen concentration of the available allergens.

Study burden and risks

The burden for the patient in this study consists of 2 blood donations of 100 ml, for this study. The patient has no direct benefits from the study. The risks of blood sampling are negligible.

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

- * > 18 years of age
- * cow's milk/peanut/nut allergy proven by DBPCFC (or in severe cases by clear history)
- * specific IgE cow's milk/peanut/nuts >0.35 kU/L

Exclusion criteria

- * other systemic diseases
- * immune-compromised
- * systemic treatment with immuno-modulatory drugs

Study design

Design

Study type: Observational invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL Recruitment status:

Recruitment stopped

4 - Analysis of the potency of individual allergens in relation to IgE recognition i ... 14-05-2025

Start date (anticipated):	25-11-2011
Enrollment:	90
Туре:	Actual

Ethics review

Approved WMO	
Date:	12-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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 CCMO **ID** NL36635.041.11