# Predictive model for the sensitising capacity of novel nutritional proteins.

Published: 07-07-2022 Last updated: 05-04-2024

Development of new in vitro assays with blood from well-characterized allergic donors.

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

## **Summary**

## ID

NL-OMON51765

**Source** ToetsingOnline

Brief title PREFER study

## Condition

• Allergic conditions

Synonym allergy, Food hypersensitivity

**Research involving** Human

## **Sponsors and support**

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** NWO-TKI nummer: LWV200123

## Intervention

Keyword: Food allergy, Immune cell activation, Novel food proteins, Skin Prick Test

#### **Outcome measures**

#### **Primary outcome**

IL-13 (biomarker) production by human donor blood cells in the new in vitro

assays.

#### Secondary outcome

not applicable

# **Study description**

#### **Background summary**

Sustainability considerations require the replacement of animal proteins by plant- or microbe-based alternatives, and stimulation of the valorisation of waste streams from existing processes. There is a fast-growing demand for the production of these (vegetable) proteins that, before they can be used commercially, must be tested for safety before consumption. One of the most important safety aspects is screening new products for their potential to cause an allergic reaction. In order to be able to predict whether a (novel) food can cause an allergic reaction, the specific proteins that make up the food must first be identified. An allergic reaction only occurs if the person is sensitized. The person then makes specific IgE antibodies against the allergen. There are no suitable animal models available to predict an allergic reaction in humans.

The assays to be developed will be based on an already existing analysis of in vitro assays described in the \*adverse outcome pathways\* (AOP) developed for food allergy by ImpARAS; the European Allergy Expert Consortium.

The aim of this research project is to develop and test new in vitro assays that can predict an allergic reaction in vitro. The blood of patients with a known food allergy is used.

#### **Study objective**

Development of new in vitro assays with blood from well-characterized allergic donors.

#### Study design

Observational study with interventions.

#### Study burden and risks

During visits 1, 2 and 3, a physical examination with blood pressure measurement and listening to the heart and lungs will take place. During visit 1, a questionnaire about allergic complaints and a diet-specific questionnaire are administered. A Skin Prick Test (SPT) is performed with a history of suspected food allergen (peanut (n=7), or cow's milk (n=7), or chicken egg (n=7). Subject is only tested with one of the three food allergens A red itchy bump may develop 15 minutes after the SPT, which will disappear on its own. 1 tube of blood will be taken by venipuncture. A bruise may develop after the blood draw, which will disappear on its own. Visit 1 will take 1 hour. take.

During visits 2 and 3, a physical examination will take place with blood pressure measurement and listening to the heart and lungs. A double blind placebo controlled food challenge takes place (1 half day challenge with verum material, 1 other half day challenge with placebo material). Choice of which allergen (peanut, or cow's milk, or chicken egg) is made on the basis of the history and the result of the SPT. Participant is only challenged with one of the three food allergens. Blood is taken through an infusion line that is standard inserted during food challenges. An allergic reaction may develop after the DBPCFC, which will disappear after taking an antihistamine. The risks are limited by starting with a minimal amount of the allergen and gradually increasing the dose at 30 minute intervals. Complaints are monitored via a PRACTALL score list. There is always a doctor and a nurse on the ward. A bruise may develop after insertion of the IV line, which will disappear on its own. Visits 2 and 3 will take 4 hours each.

For subjects who have undergone a positive DBPCFC with the suspected food allergen from the anamnesis and SPT, 100 ml of blood is collected during visit 4 by means of a venipuncture. A bruise may develop after the blood draw, which will disappear on its own. Visit 4 will take 0.5 hours.

# Contacts

**Public** Erasmus MC, Universitair Medisch Centrum Rotterdam

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## **Trial sites**

## **Listed location countries**

Netherlands

## **Eligibility criteria**

Age Adults (18-64 years)

#### **Inclusion criteria**

Signed informed consent 18 years of age or older, mentally competent Patients suspected of a food allergy to peanut, or cow's milk, or hen's egg Complaints after consuming peanut, or cow's milk, or hen's egg Positive Skin Prick test with peanut, or cow's milk, or hen's egg

## **Exclusion criteria**

Patient eats peanut, or cow's milk, or hen's egg, without complaints Negative skin prick test with peanut, or cow's milk, or hen's egg Negative DBPCFC with peanut, or cow's milk, or hen's egg Antihistamines used in the last 72 hours before the skin prick test and/or DBPCFC Unable to stop beta-blockers

Use of more than 10 mg prednisone (relative contraindication)

## 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):	11-07-2022
Enrollment:	30
Туре:	Anticipated

# **Ethics review**

Approved WMO	
Date:	07-07-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Not approved	
Date:	23-01-2023
Application type:	Amendment
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** CCMO **ID** NL79534.078.21