Measurement of sensitization to novel nutritional proteins

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The aim of this study is to compare results of sensitization measurements (positive or negative) in skin test and blood test, with new nutritional proteins in food-allergic patients.

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

Summary

ID

NL-OMON56286

Source
ToetsingOnline

Brief title
PREFER II 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: Topsector TKI Agri & Food LWV200123 (PPS toeslag); nationale EZ subsidie,Arla foods Ingredients,Cargill R&D Centre Europe,Nestlé,Nutricia,Seaweed Company

Intervention

Keyword: Food allergy, Novel food proteins, Skin Prick Test

Outcome measures

Primary outcome

Positive sensitization in skin test [>3 mm ø] and in blood (positive IL-13

release) with novel food proteins

Secondary outcome

nvt

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. An allergic reaction only occurs if the person is sensitized. This involves the presence of specific immunoglobulin E (sIgE) against the relevant allergen (sensitization), demonstrated in the skin prick test (SPT) or in the blood. Without the presence of specific IgE, the patient cannot react allergically to a protein. No suitable animal models are available to predict sensitization in humans. The aim of this study is to compare results of sensitization measurements (positive or negative) in skin test and blood test, for new nutritional proteins in food-allergic patients.

Study objective

The aim of this study is to compare results of sensitization measurements (positive or negative) in skin test and blood test, with new nutritional proteins in food-allergic patients.

Study design

Observational study with interventions

Study burden and risks

During the visit, an SPT (maximaal N= 9) will be performed with extracts of novel foods, phylogenetically/biologically related to the proteins to which the patient is proven to be allergic. These novel foods are supplied by industry and the patient is tested with a maximum of 6 novel food proteins (2 proteins per industry, maximum 3 industries) per patient. This is to keep the burden on the patient as low as possible. Differences between the 2 samples per industry, lies in the pre-processing such as heated or unheated, frozen or freeze-dried, protein isolate or whole product. The biological background remains unchanged. For the skin prick test (SPT), a choice is made per individual patient from the proteins of the seven industries, with a maximum of 3 industries.
Only proteins from Industries are chosen that are phylogenetically/biologically related to proteins to which the patient is food allergic. Proteins from other industries that are phylogenetically/biologically unrelated to the proteins to which the patient is food allergic are not tested in the patient.
Example: A patient is allergic/sensitized to wheat. There is 1 company that supplies a new wheat-related protein: Cargill R&D Center Europe. The patient is only tested with 2 new comparable proteins from this company in addition to the usual 3 controls. (total 5) Another patient is allergic/sensitized to cow's milk. There are three companies, each with 2 new cow's milk-related proteins. 3x2 new proteins are tested. Proteins from other industries are not tested in the.
A red itchy bump may develop 15 minutes after the SPT, which will disappear on its own. Reactions elsewhere in the body do not occur with an SPT, not even with new food allergens. The extracts are made in-house in a 10% solution in PBS as stated in the current protocol in KIS. 3 tubes of blood are taken. A bruise may develop after the blood test, which will disappear on its own. The visit will take 1 hour.

Contacts

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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 diagnosed with a food allergy
Sensitization (Positive skin test [>3 mm ø] or positive specific serum IgE [> 0.35 kU/L]) to at least 1 protein phylogenetically/biologically related to a new protein supplied by the industry.

Exclusion criteria

Patient does not have a food allergy
Antihistamines used in the last 72 hours before the skin prick test
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:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-02-2024
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	26-10-2023
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	NL83872.078.23