

Food allergy to soy:

"Characteristics of soy allergy profiles in relation to the severity of the symptoms after ingestion."

Published: 25-11-2014

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To investigate causes and predictors for primary or secondary allergy profiles for soymilk

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Food intolerance syndromes
Study type	Observational invasive

Summary

ID

NL-OMON39594

Source

ToetsingOnline

Brief title

Soy study

Condition

- Food intolerance syndromes
- Upper respiratory tract disorders (excl infections)
- Angioedema and urticaria

Synonym

Food allergy, IgE mediated 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: allergy, DBPCFC, food, soy

Outcome measures

Primary outcome

Clinical response to DBPCFC with soy

Secondary outcome

Presence of specific IgE antibodies and predictive value of specific IgE

recombinant antibodies against various soy allergens

Study description

Background summary

Food allergie to soy can cause a severe reaction. If the soy allergy is caused by crossreactivity to Tree Pollen, (secondary sensitization) the symptoms are expected to be mild. However, there is also a serious form of soya allergy whereby it is independent from cross-allergies. (primary sensitization) The different profiles of these forms of soy allergy are only partly known.

Study objective

To investigate causes and predictors for primary or secondary allergy profiles for soymilk

Study design

Prospective observational study in which patients (> 18 years) will be approached for 2 years.

Intervention

Double blind placebo controlled food challenge with soy
Skin prick tests
One blood sample

Completing 3 questionnaires

Study burden and risks

Participants will visit the hospital 3 times.

In all patients a blood sample will be drawn. Questionnaires will be completed. Also skin tests will be performed. A blood sample will be drawn. Next, a DBPCFC will take place on two different days. After the last challenge the results and recommendations will be discussed.

The burden and risks will be minimal due to extensive experience with DBPCFCs. Nevertheless, we are aware, that the outcome of the DBPCFC is unpredictable and reactions may occur in the patients. The risk to the patient will be limited given the extensive experience in the outpatient clinic allergology in the field of food challenges. All required facilities are available (emergency medication, adequate medical staff)

The possible benefit for the patient is a clearer diagnosis (by means of the DBPCFC) concerning their possible IgE mediated soy allergy and thus better dietary and lifestyle counselling.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients (adults > 18 years) with a Tree pollen allergy and a possible soymilk allergy.

Exclusion criteria

Receiving subcutaneous immunotherapy for birch pollen. Inability to stop antihistamines, pregnancy, suspect for non-IgE mediated reactions, inability to speak and understand Dutch language, using medication affecting provocation: e.g. prednisone, cyclosporine, montelukast, sensitization to the used DBPCFC products (except soy)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2015
Enrollment:	133
Type:	Actual

Ethics review

Approved WMO

Date: 25-11-2014

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	NL41157.078.12