Determination of Minimum and Non-provoking Doses of Soy Protein in Soy Allergic Individuals

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The purposes of this study are to determine a threshold level for soy protein when consumed by soy-allergic individuals.

Ethical review	Not approved
Status	Will not start
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON34810

Source
ToetsingOnline

Brief title
Determination of minimum and non provoking doses of soy.

Condition

- Allergic conditions

Synonym
food allergy, soy allergy

Research involving
Human

Sponsors and support

Primary sponsor: FARRP: Food Allergy Research and Resource Program
Source(s) of monetary or material Support: FARRP (= Universiteit van Nebraska;USA)

Intervention

Keyword: food allergy, soy allery, threshold levels

Outcome measures

Primary outcome

Individual threshold level of soy proteine (in mg.)

Group threshold levels of soy proteine (in mg.)

Secondary outcome

Determination of the relevant allergens of soy

Determination of the relation between allergen recognition pattern and severity

of the allergy

Study description

Background summary

Soy-allergic individuals and their clinicians would benefit from knowing their individual minimum eliciting dose for soy protein. This information is beneficial in that it assists the clinician and the individual in assessing clinical reaction risk and in implementing suitable avoidance diets.

Soy-allergic individuals will also benefit because the food processing industry and government agencies that regulate it will improve their practices as a result of knowledge gained regarding the minimal eliciting dose for soy protein.

Determining the thresholdlevel for a group of soy-allergic individuals will also be beneficial in the development and refinement of immunoassay tests used to detect soy residues in foods.

Additionally, ingredients derived from soy are ubiquitous in the food industry and include soy flour (used in this study), soy oil, lecithin, soy protein concentrates and isolates, and soy sauce. Some of these soy-derived ingredients contain high percentages of soy protein (soy flour, soy protein

concentrates and isolates) while others contain very low amounts of soy protein (soy lecithin and soy oil). Currently, soy-allergic consumers are advised to avoid all soy-derived ingredients. But, with knowledge of the thresholdlevel for soy protein, it may be possible to advise soy-allergic individuals that certain soy-derived ingredients are safe to consume.

The serum will be used for testing specific immunoglobulin E (IgE) for soy. This can be used in further research.

Study objective

The purposes of this study are to determine a threshold level for soy protein when consumed by soy-allergic individuals.

Study design

World wide 29 soy allergic individuals wil be included.
5-10 Dutch patients will be included via the allergy outpatient clinic from the University Medical Center Utrecht

Visit1:
If the resulsts of the blood- and skin prick test (SPT) are older than 6 months, they will be performd again.
A special questionnaire will be filled in.

If the results of the SPT and IgE-soy are positive the patients are invited to the challenges

Visit 2+3:
A double blind challenge will be pergormed over 2 days.
One day the portions will contain soy flour, and one day the porions will be placebo.
Randomisation will take place by the shake of a die.
The blinded portions will be prepared by FARRP
Patients will be challenged with five 20 grams portions of soy four in a granola cereal or with placebo portions.
The doses will be given with a 30 min. interval
Doses are : 0.1 mg, 1,0 mg 10 mg, 100 mg, 1000 mg soy protein.
The doses will be repeated once if there is a question about the objectivety of the reaction.
If there is no reaction on both days, a open challenge will be performed at the end of day 2.
the open challenge consits of 8 ounces of commercially availeble soy milk
On both challenge days the patients will get a periferal drip, though which also the bloodwithdrawel can take palce of the 50-80 ml blood.
Afterwards the patients have a cunsultation with the doctor and if necessary

with the dietician.

Patients have to temporary stop antihistamines 3-7 days before the SPT and the challenges.
Patients may not use caffeine and alcohol 24 hours before the challenges.

Intervention

The intervention that may take place during the screening:
A skin prick test.
Only if the results of the IgE for soy are older than 6 months, this will be determined again.

After inclusion a double blind placebo contolled food challenge will be performed:
- Patients will get an intravenous line, to administer medication if necessary.
-The patientes have to eat portions muesli, which may contain, increasing doses of soy proteine.
If an objective allergic reaction has taken place, the challenge will stop, and medication will be administerd, to decrease the reaction.

Study burden and risks

Visit 1:
The burden in visit 1 is low.
Visit 2+3:
To confirm the diagnosis and to determine the threshold level according to international guidelines, it is necessary that objective symptoms occur during the challenge, or persistent subjective symptoms. Mostly these symptoms are relatively mild to moderately severe. (Itch in mouth, urticaria, nausea, stomach ache). These symptoms are similar to the symptoms that the patients experience when they ate something wrong.
Sometimes the symptoms have a more severe character. (tightness of the throat, vomiting, angioedema). Patients react -almost always- directly when medication is administered (corticosteroids, antihistamines, and sometimes epinephrine). Sometimes it takes several hours for the symptoms to disappear completely. If needed, patients can stay a night at the dermatology ward. In the regularly patient care this is included also.
Determining the threshold level is important for multiple reasons. For the present and future diet of the patient, for the food industry, for the governments and for further research in diagnostics and treatment of food allergy.

(We want to indicate that we agreed with the sponsor to challenge between 5 and 10 patients. In this form you can only indicate one number, and not two

numbers.)

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Soy allergic people with the age of 18-70 years, with a positive specific IgE for Soy and a positive SPT for 2 soy extracts (made from the soy flour, used in the challenges / and for the extract used in the outpatient clinic: from ALK).

Exclusion criteria

Allergy for wheat, oats, cinnamon, applejuice, corn;

pregnancy / lactation, instable asthma

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Ethics review

Not approved

Date:	04-02-2011
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	ID
CCMO	NL30069.041.09