Determination of minimum and non-provoking doses of soy protein in soy allergic individuals

Published: 19-08-2013
Last updated: 01-05-2024

Primary Objective: To determine minimum and non-provoking doses of soy protein (in mg) for soy allergic individuals Secondary Objective(s): To determine the relevant allergens of soy in soy allergy and to determine the relation between allergen...

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

Summary

ID

NL-OMON39595

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, Department of Food Science & Technology, University of Nebraska
Source(s) of monetary or material Support: FARRP;University of Nebraska;USA

Intervention

Keyword: food allergy, soy allergy, threshold level

Outcome measures

Primary outcome

To determine minimum and non-provoking doses of soy protein (in mg) for soy allergic individuals.

Secondary outcome

To determine the relevant allergens of soy in soy allergy and to determine the relation between allergen recognition pattern and severity of the allergy.

Study description

Background summary

The purposes of this study are to determine a lowest observed adverse effect level (LOAEL) and to establish a no observed adverse effect level (NOAEL) for soy protein when consumed by soy-allergic individuals. 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. For example, the food industry uses shared equipment for soy-containing and soy-free products. The level of care needed for sanitation of shared food processing equipment to assure its safe use is uncertain. As a result, many foods are labeled with precautionary statements such as *may contain soy*. The establishment of a LOAEL and a NOAEL will provide guidance to regulators and the food industry in the establishment of circumstances where residual levels of soy protein from shared processing equipment warrant the use of precautionary labeling. Soy-allergic individuals will benefit from these food industry and government regulatory agency actions because they should result in the availability of a wider variety of safe food choices.

Study objective

Primary Objective: To determine minimum and non-provoking doses of soy protein

(in mg) for soy allergic individuals
Secondary Objective(s): To determine the relevant allergens of soy in soy allergy and to determine the relation between allergen recognition pattern and severity of the allergy.

Study design

The study design will be cross-sectional. Subjects will be identified by a blood draw and a skin prick test. Twenty-nine soybean allergic individuals will be selected as subjects and challenged with a double blind placebo controlled food challenge based on well established international guidelines. In the UMCU 10 subjects will be included.

Intervention

Not applicable

Study burden and risks

Benefits: The direct benefit to the subject is to know what amount of soy flour is an allergy risk for him or her. Results from all o f the subjects will be used to help determine regulatory and industry labeling policies for food products produced in facilities that also manufacture foods containing soy flour.
Risks: Skin prick testing is considered a relatively safe procedure and is performed daily in allergy clinics. The most common side effect is the development of an itchy spot (like a mosquito bite) in the area of skin where a positive reaction occurs. The itchiness resolves after a few minutes and the skin lesion should resolve within an hour or two.
The drawing of blood from subjects is also an everyday procedure but side effects may occur. The most common side effect is a small discoloration or bruise that may remain at the site for several days.
The reactions that can occur with food challenges are often mild or moderate. We note that there are risks associated with food challenges, but these risks are reasonable since challenges are performed under the guidance of an experienced practitioner in a properly equipped setting and the soy dosages will be increased gradually. Nursing and physician staff will be present during the oral food challenge. In the event that the subject has a reaction during the oral food challenge, emergency supplies and medications will be available and be administered according to the level and severity of reaction. The precise risk of anaphylaxis from the food challenge is unknown but is very low.

Contacts

Public
FARRP; Food Allergy Research and Resource Program, Department of Food Science & Technology, University of Nebraska

Food Industry Complex 143
Lincoln, Nebraska 68583-0919
US
Scientific
FARRP; Food Allergy Research and Resource Program, Department of Food Science & Technology, University of Nebraska

Food Industry Complex 143
Lincoln, Nebraska 68583-0919
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Convincing clinical history of a Type I allergic reaction caused by eating soybeans or soy flour
2) Positive skin prick test to the extract of soy flour used to make the oral challenges AND positive specific immunoglobulin E (IgE) to soy (CAP-RAST, Pharmacia Uppsala, Sweden). Subjects should also be skin prick tested with a commercial soy extract.
3) Adults (18-70 years)

Exclusion criteria

1) Subjects with allergy to wheat
2) Pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2014
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	19-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-06-2014
Application type:	Amendment
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	NL38791.041.11