Sensitization to lupine flour: is it clinically relevant?

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Food intolerance syndromes
Study type	Interventional

Summary

ID

NL-OMON29872

Source
ToetsingOnline

Brief title
allergy to lupine flour

Condition

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

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: Fa. Wed. W. Miedendorp

Intervention

Keyword: allergy, DBPCFC (Double Blind Placebo Controlled Food Challenge), Lupine flour, SPT (skin prick test)

Outcome measures

Primary outcome

Skin tests with lupine flour, peanut and soy. Reactions on DBPCFC's. Presence

of specific IgE against lupine flour in the serum of the patient.

Secondary outcome

Presence of cross - reacting allergenes.

Study description

Background summary

Lupineus Augustifolius (blue lupine, Australia) is used for human and animal consumption. Lupine seeds have been part of normal food intake since the introduction of lupine flour as an ingredient in wheat flour in the 1990s for its nutritional and food-processing qualities, lupine consumption became more widespread in Europe. The frequency of allergic reactions to lupine in the general population is unknown. Allergic reactions to lupine have been documented. One anaphylactic reaction has been documented. Cross- reactivity to peanut is most likely. The only method to confirm an IgE mediated food allergy is to perform a double blind placebo controlled food challenge. (DBPCFC) This appears to be the "golden standard" to confirm an IgE mediated food allergy.

Study objective

We found a prevalence of 6% sensitization in patients with a possible food allergy. The aim of this study is to investigate if sensitization to lupine flour in atopic patients has clinical relevance. Additionally, we want to investigate if cross- reactivity is responsible for co- sensitization to peanut.

Study design

From October 2004 till October 2005 we have performed skin prick tests (SPT) with lupine flour, peanut and soy extracts, in consecutive patients of the

Department of Allergology, with a suspected food allergy. Co-sensitization is examined and Histamine Equivalent Prick test (HEP) index is calculated. Complaints after intake of lupine flour containing food, is administered.
A selection will be made of patients with positive sensitization (HEP > 0.15) for lupine flour. The patients will be asked to participate in further investigations. This will comprise a questionnaire, Double Blind Placebo Controlled Food Challenge (DBPCFC), Radio Allergo Sorbent Tests (RAST), and if necessary RAST- inhibition tests.

Intervention

Patients will be asked to undergo DBPCFC. They will intake lupine flour that is hidden in small cookies. It may be possible that lupine flour is not a part of the diet of the patient and in that case it may be called an intervention.

Study burden and risks

The duration of the visit amounts 3 hours on two different days. One sample of blood will be taken on the first day. Complaints after the intake of lupine flour will be gathered by a questionnaire.
A systemic adverse reaction during a PCDBFC is rare, because only a minimal amount af allergen is used in the first provocation. If the patient develops a reaction, the provocation will be interrupted and a tablet of anti histaminicum will be administered. When the complaints are disappeared the patient may go home.
Escape medicatie available, physician nearby.

Contacts

Public
Fa. WEd. W. Miedendorp

dr. Molewaterplein 40
3015 GD Rotterdam
Nederland
Scientific
Fa. WEd. W. Miedendorp

dr. Molewaterplein 40
3015 GD Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with a possible food allergy (complaints after intake of certain food) and a positieve skin test (HEP (Histamine Equivalent Prick test) index > 0.15) with lupine flour - and peanut extract. Older than 18 years

Exclusion criteria

pregnancy, inability to stop anti histamines, using medication affecting provocation: e.g. prednison, cyclosporine, montelukast

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2006
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	21-11-2006
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	NL12945.078.06