Improvement of Diagnostic mEthods for ALlergy assessment. Cashew allergy in children as a showcase (IDEAL study).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29522

Source
NTR

Brief title
IDEAL

Health condition

Allergy to cashew nuts

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Technologiestichting STW

Intervention

Outcome measures

Primary outcome

Results mediator release assays in comparison with the existing tests.

Secondary outcome

1. Adverse events;

2. Prevalence of cashew nut allergy.

Study description

Background summary

There is an urgent need for improvement of the diagnostic tools foorfood allergy. Current tests jeopardize proper diagnosis due to poor sensitivity and false-positive and false-negative results. The current Standard is the double blind, placebo controlled food chanllenge test. This test is expensive. time consuming and includes the risk of allergie reactions. In addition this test is time consuming and can therefore only be performed in approx. 10% of patients. This means that in 90% of patients incomplete diagnostics are performed. This group is gets dietary advice, while it is uncertain whether they really need this. Mediator Release Assays (MRA) are promising tests for superior results in comparision to the current diagnostic tests, because of a superior relationship with the in-vivo situation. MRAs will result in a more relevant diagnosis, less burdenful test protocols for patients and a significant reduction of costs of food challenges. The prevalence of allergy to cashew in children is incresing considerably. The prevalence is unknown and to date no studies addressing the best diagnostic tools have been performed. This study will provide knowledge about the severity and prevalence of this type of allergy and it is expected thatthe newtest method will make the food challenge test redundant.
Because the food challenge test is only performed in 10% of regular patients, this test is seen as a study related test in this study and not as being part of regular diagnostics.

Study design:

Therapeutic non-drug intervention study.
Therapeutic, because the patiënt directly benefits forthe improved diagnostic actions. The diagnosis is more solid and
therefore the dietary councelling can be better targetted.

Conventional diagnostics.

Plus for study purposes:

1. Double blind randomized food challenge test;

2. 6 skin prick tests;

3. Blood draw (12 ml) for Mediator Release Assays

Questionnaires.

200 patients.

Duration approx.2 months per patient.

Patient population:

Children 2 to17 (inclusive) years with suspected allergy to cashew nuts.

Written IC of parents (guardian) and -in case child is 12 years of age or above- also of child.

Study objective

The hypothesis is that an accurate history, conventional markers of sensitization, IgE antibodies in the serum and positive SPT, and more advanced techniques (MRAs and component resolved diagnosis (CRD)) might predict clinical allergy to cashew nuts. Thereby, the aim of this study is to improve diagnostic procedures for food allergies.

Study design

Week 8.

Intervention

1. Double-blind randomized food challenge;

2. Extra skin prick test;

3. Extra blood sample (12 ml);

4. Completion of questionnaires.

Contacts

Public
Afdeling Allergologie
Erasmus MC
Postbus 2040
N.W. Jong, de

Rotterdam 3000 CA
The Netherlands
Scientific
Afdeling Allergologie
Erasmus MC
Postbus 2040
N.W. Jong, de
Rotterdam 3000 CA
The Netherlands

Eligibility criteria

Inclusion criteria

1. Age: 2-17 year;

2. Children with a positive skin prick test (HEP > 0.21) and/ or detectible sIgE (>0.35) to cashew nut;

3. History of positive reaction to cashew nut or an unknown reaction (because of never ingested);

4. Written informed consent parents and child (≥ 12 year old).

Exclusion criteria

1. History of severe or uncontrolled asthma (investigator’s opinion);

2. Severe eczema defined as TIS (Three Item Severity) eczema score (> 6);

3. Immunological diseases, cardiovascular diseases or malignity;

4. Severe psychosocial problems;

5. Not able to stop anti-histamine medication for a short period;

6. Use of beta-blockers;

7. The patient is allergic to one or more of the ingredients of the food matrix, unless a suitable substitute for the ingredient in question can be found;

8. Unable to speak and understand the Dutch language properly;

9. Not willing to comply with the study procedures.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2012
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-08-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41456
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3422
NTR-old	NTR3572
CCMO	NL39127.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41456

Study results

Summary results
N/A