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

Published: 19-04-2012
Last updated: 15-05-2024

To improve diagnostic tools for food/cashew nut allergies with the use of Mediator Release Assays.Genetic component of cashewnut allergy.

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

Summary

ID

NL-OMON41456

Source
ToetsingOnline

Brief title
IDEAL

Condition

- Food intolerance syndromes

Synonym
food allergy, IgE mediated allergy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: STW (krijgt fondsen voor 60% van NWO en 40% van ministerie van EZ)

Intervention

Keyword: Allergy, Cashewnut, Diagnosis

Outcome measures

Primary outcome

Results of Mediator Release Assays in comparison with regular tests.

Secondary outcome

Adverse events, prevalence of allergy to cashew nuts.

Genetic research.

Study description

Background summary

There is an urgent need for improvement of the diagnostic tools for food 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 challenge test. This test is expensive. time consuming and includes the risk of allergic 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 comparison to the current diagnostic tests, because of a superior relationship with the in-vivo situation. MRAs will result in a more relevant diagnosis, more convenient test protocols for patients and a significant reduction of costs of food challenges. The prevalence of allergy to cashew in children is increasing 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 new test 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.

Protocol amendment Feb-14:
Some children already reacted positively during the first (=lowest concentration cashew nut) or second step of the provocation test. This applies

to approx. 15 patients in Erasmus MC and approx. 5 patients in UMCG . The extra tests will not be performed in the Reinier de Graaf Gasthuis.
It is relevant for the children to assess the actual no effect level. This has also scientific relevance.
The parents of these children and the children themselves (if 12 years or above) will be contacted to ask for their consent to conduct 2 extra provocation tests: 1 with and 1 without cashew nut. De starting concentration will be considerably lower than during the previous provocation test.

Protocol amendment Jan-15::
90% cross reactivity in the skin test has been found between cashew and pistache. So far 75% of the provocations with cashew have been positive, so it is important to know whether these children can use pistache or not. For this reason the PI would like to add an extra double blind provocation (plus 1 blood draw) with pistache to the study.
There is also cross reactivity with mango (35%). An open provocation with mango is also added to the study.
De studie wordt bij patiënten uit Rotterdam en Delft uitgevoerd. Alle testen gebeuren in Rotterdam.

Study objective

To improve diagnostic tools for food/cashew nut allergies with the use of Mediator Release Assays.
Genetic component of cashewnut allergy.

Study design

Therapeutic non-drug intervention study.
Therapeutic, because the patient directly benefits for the improved diagnostic actions. The diagnosis is more solid and therefore the dietary counseling can be better targeted.
Conventional diagnostics
Plus for study purposes:
Double blind randomized food challenge test
6 skin prick tests
Blood draw 12 ml for Mediator Release Assays and 7 ml (alternative: saliva test) for genetic research.
Questionnaires.
200 patients.
Duration approx.2 months per patient.

Intervention

Double blind food challenge test, skin prick tests, blood draw, questionnaires.

Study burden and risks

Risk: allergic reaction to food challenge and skin prick test.
Burden: study duration approx. 8 weeks.
Skin prick tests.
Blood draw (19 ml extra for the study).
Questionnaire quality of life (parents and children of 8 years and above) during visit 1 and after approx. 6 months.
Food challenges (double blind, randomized), time interval 2 weeks.
Amendment Jan-15: 1 extra double-blind set of 2 provocation tests (pistache) and 1 open-label provocation test with mango, plus approx. 5 ml blood.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Patients with a possible cashew nut allergy and a positive skin test (Histamine Equivalent Prick HEP > 0.2) or a positive CAP FEIA (> 0.35) with cashew nut extract.
Age 2-17 (incl.) years.
Written consent of parents (guardian) and -if 12 years and above- the patient.

Exclusion criteria

Severe or uncontrolled asthma and/or recent (< 1 year) intensive care unit admissions.
Severe eczema defined as TIS (Three Item Severity) eczema score (> 6).
Immunological diseases, cardiovascular diseases or malignancy.
Severe psychosocial problems.
Not able to stop anti-histamine medication for a short period.
Use of beta-blockers.
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.

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):	20-05-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	19-04-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-02-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-04-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-07-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-01-2015
Application type:	Amendment
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

ID: 29522
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	Nederlands Trialregister, registratienummer TC3572
CCMO	NL39127.078.12
OMON	NL-OMON29522