Determining eliciting doses in walnut allergic patients

Published: 25-01-2012
Last updated: 01-05-2024

Establishing an eliciting dose distribution for walnut on population level by determining individual eliciting doses in double-blind placebo controlled food challenges.

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

Summary

ID

NL-OMON41503

Source
ToetsingOnline

Brief title
Determining eliciting doses in walnut allergic patients

Condition

- Allergic conditions

Synonym
food allergy, walnut allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,TNO;Innovation for Life;Zeist

Intervention

Keyword: eliciting dose, food allergy, walnut allergy

Outcome measures

Primary outcome

Establishing an eliciting dose distribution for walnut on population level by

determining individual eliciting doses in double-blind placebo controlled food

challenges.

Secondary outcome

Identifying biomarkers that play a role in a food allergic reaction.

Study description

Background summary

Most patients with food allergy adhere strictly to their diet to avoid the relevant food. Therefore, most reactions take place by hidden allergens or suboptimal labeling of food products. Good labeling is essential in preventing food allergic reactions. The current legislation is inadequate.
A first step in improving laws and regulations is to quantify the effects of certain concentrations of allergens in products. This requires knowledge of eliciting doses. The eliciting dose is defined as the lowest amount of allergen that is required to elicit an allergic reaction and is derived from double-blind placebo-controlled food challenges which are also used in routine daily practice to diagnose a food allergy.
At this moment, eliciting doses for some well-known food products that can trigger an allergic reaction (peanut, hazelnut, milk, egg) have been established by food challenges in representative populations. For walnut these data are still lacking while it is the third most common food allergy in the Netherlands and the fourt most common in Europe.

Study objective

Establishing an eliciting dose distribution for walnut on population level by determining individual eliciting doses in double-blind placebo controlled food challenges.

Study design

Visit 1: characterization of patients by skin prick test and blood tests
Visit 2 and 3: food challenge
Visit 4 (only in case of a positive food challenge and after particular informed consent for this extra visit): blood withdrawal

Intervention

Food challenge with walnut food for all participants

Study burden and risks

First visit: 1 hour and 2 provocation days of each 8 hours, possible 4th visit of 30 minutes. The skin prick test is a safe test and is routinely performed in the outpatient department clinic. In most cases, the participant will get a wheal (looks like a mosquito bite). The itching disappears after 15-30 minutes and the wheal itself after about 2-3 hours. The risk of the blood collection and intravenous drip during food challenge is a slight pain and the possibility of a bruise.
The result of a food challenge is an allergic reaction that can range from mild symptoms (itching in the mouth) to a (rarely) anaphylactic reaction. During provocation, there are good precautions to minimalize the risk: medications can be administered immediately by the intravenous drip if needed and there will be a continuous observation until 2 hours after provocation by experienced nurses who work daily with food challenges. The whole food challenge is performed under the supervision of a physician.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 GA
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age 18 years or older
- suspected history of adverse type I allergic reaction to walnut

Exclusion criteria

- congenital/acquired immune disorder
- lymfoproliferative disease
- use of systemic immune suppressants
- pregnancy
- use of beta blockers
- severe asthma, defined as FEV1 < 70%

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2012
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	25-01-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-07-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-11-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-12-2015
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	NL38180.041.11