Prediction of short and long term food challenge outcome in children

Published: 12-02-2013
Last updated: 24-04-2024

The overall aim of this study is to find objective and sensitive markers to predict short term and long term food challenge outcome. Primary Objectives: - Can we predict (severity of) short- and long-term food challenge outcome with clinical and...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37019

Source
ToetsingOnline

Brief title
PROOF study

Condition

- Other condition

Synonym
Food allergy

Health condition

Voedselallergie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Food allergy, Food challenge, Peanut allergy

Outcome measures

Primary outcome

- Differences between children with positive and children with negative

short-term food challenge outcome

- Differences between children with positive and children with negative long

term food challenge outcome

Secondary outcome

Clinical parameters measured during challenge to discriminate between children

with positive and negative short term food challenge outcome

Symptom Scores, VAS-scores, heart rate, saturation, breathing pattern, FEV1,

blood pressure, temperature, VAS-scores, dermographism and eczema scores.

Study description

Background summary

At present, the double blind placebo controlled food challenge (DBPCFC) represents the gold standard for the definitive diagnose of food allergy. The DBPCFC is terminated and considered positive when objective symptoms occur. However, there are several pitfalls in performing and interpreting food challenges. Food challenges are expensive due to the time consuming procedure and the need of trained staff. Moreover challenges can be dangerous by bearing the risk of a severe allergic reaction. In children, the portion size and total volume of the challenge food can be a problem. Furthermore, especially in young children, symptoms during challenge can be difficult to interpret. Subjective

symptoms (abdominal complaints, oral allergy syndrome, change of behaviour) are difficult to objectify and without extensive monitoring; less obvious objective symptoms (as mild bronchoconstriction or change in blood pressure) are easily missed. As a result false-negative tests do occur and negative challenges are sometimes followed by an allergic reaction upon the reintroduction of the allergen. With this study we aim to predict short term and long term food challenge outcome with regular available patient data and objective clinical and laboratory measurements before, during and after food challenge. Hereby we tend to reduce the amount of food challenges by at least 50%.

Study objective

The overall aim of this study is to find objective and sensitive markers to predict short term and long term food challenge outcome.

Primary Objectives:
- Can we predict (severity of) short- and long-term food challenge outcome with clinical and laboratory markers measured before food challenge in children with suspected food allergy?

Secondary Objective:
- Can we identify objective clinical markers measured during food challenge, to predict short term and long term food challenge outcome?
- What is the incidence and type of (accidental) allergic reactions during follow up of positive and negative food challenges?
- Can we find predictors for reintroduction problems after negative food challenge?

Study design

In this observational study we will use regular available clinical data and food allergy diagnostics to predict (severity of) food challenge outcome (short term and long term) in children with suspected food allergy for peanut. Moreover we will measure in vivo clinical paramters during food challenge to objectify food challenge outcome. For long term food challenge outcome we will monitor subjects during 12 months after food challenge.

Study burden and risks

We will study children because it is important to diagnose food allergy at a young age to prevent unnecessary restricted diets further in live. Moreover, especially in children subjective reactions during challenge occur and subtle reactions are difficult to objectivity. Therefore especially in children it is important improve the diagnostics tools to detect food allergy and where possible, reduce the amount of challenges.
There are no risks associated with participation to this study. There are no

individual patient benefits for the participation of this study. In the future, the results of this study can lead to an improved diagnostic procedure in patients with suspected food allergy and prevent children from challenge, more over this study can lead to ore objective food challenge test outcomes.

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

- Child is between 1 * 18 years old
- Suspected food allergy for peanut by:
1) Raised specific IgE for peanut and/ or positive skin prick test for peanut without previous known
ingestion of the allergen, or;

2) Objective immediate type clinical signs or symptoms (within 2 hours) after ingestion of peanut or
repetitive subjective clinical signs or symptoms after ingestion of peanut with or without raised
specific IgE for peanut / positive skin prick test for peanut; or
3) Objective immediate type clinical signs or symptoms (within 2 hours) after the ingestion of an unknown allergen and raised specific IgE for peanut / positive skin prick test for peanut.;-
Parents of the children must be able to speak, read and write Dutch language

Exclusion criteria

- Peanut is eaten regularly in a substantial amount without clinical signs or symptoms
- A previous severe life treating reaction to peanut requiring ICU submission.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Not approved

Date:	12-02-2013
Application type:	First submission
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	NL42365.041.12