Oral immunotherapy in young children diagnosed with food allergy

No registrations found.

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

Summary

ID

NL-OMON20790

Source
NTR

Brief title
ORKA study

Health condition

Food allergy

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: www.dz.nl

Intervention

Outcome measures

Primary outcome

Safety based on the number of anaphylactic reactions that occurs within 2 hours after administration of the food product. Feasibility
as assessed by both parents and doctors.

Secondary outcome

Effectiveness measured as the number of children with long-term tolerance (SU): a negative food challenge 4 weeks after the discontinuation of the OIT.

Study description

Background summary

Background of the study:
In the Netherlands, a few thousand babies develop a food allergy every year that often will lead to lifelong restrictions. Oral immunotherapy (OIT) does not lead to long-term tolerance (sustained unresponsiveness, SU) in older children and adults and has many side effects. Immunotherapy at a young age has hardiy been studied. but there are good indications that this therapy can lead to longterm tolerance. By using a lower dose of the food. the number of side effects is probably limited. Little is known about the further practical feasibility of this therapy in babies and infants.

Objective of the study:
Primary: Is OIT with Standard food products safe to perform in children aged 6 to 24 months with a proven food allergy to chicken egg, peanut, hazelnut, cashew nut and / or wheat? And what is the feasibility of OIT with a low daily dose of a Standard food product for these children? Secondary: Can OIT induce long-term tolerance (SU) in children with a proven food allergy in the age of 6 to 24 months (compared to a control group)?

Study design:
An explorative prospective intervention study combined with a control group to compare the induction of spontaneous tolerance with the induction of tolerance by OIT.

Study population:
Children aged 6 to 24 months with a proven food allergy (60 children in the intervention group and 120 children in the control group).

Intervention:
Children who are enrolled in the ORKA study start with the OIT (daily intake of a small amount of food for which the patient is allergic) within 2 weeks after the provocation test. After the maintenance dose has been reached, this will be continued for 12 months. Children come to the hospital after 6 months for an extra check. A provocation takes place 4 weeks after the
discontinuation of the OIT.

Study objective

For this feasibility study, no hypothesis have been made.

Study design

Evaluation at 6 months

Intervention

Children who are enrolled in the ORKA study start with the OIT (daily intake of a small amount of food for which the patiënt is
allergie) within 2 weeks after the provocation test. After the maintenance dose has been reached, this will be continued for 12
months.

Contacts

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Eligibility criteria

Inclusion criteria

• Children with an age of 9 to 24 months.
• A proven food allergy (positive provocation and sensitization demonstrated by a skin prick test > 3mm and / or sIgÉ> 0.35kU / L) for chicken egg, peanut, cashew nut, hazelnut and / or wheat.
• Assessment of the presence of other food allergies (Standard care) by introduction in the diet and / or the determination of sensitization. From the mentioned allergens. Introduction into the diet or the diagnosis food
allergy has been made.
• Written permission (signed informed consent form) from both parents / guardian for participation in the study.

Exclusion criteria

• Uncontrolled viral wheezing, defined as admitted to hospital > 1x in the past six months because of these complaints.
• Uncontrolled eczema.
• Severe gastrointestinal complaints such as gastroesophageal reflux disease, where an underlying disease such as eosinophilic esophagitis (EoE) cannot be excluded.
• Active EoE.
• Mastocytosis (also cutaneous).
• Psycho-social problems in the family that may be a barrier to a good daily performance of long-term therapy.
• Inability of parents to follow instructions, to recognize allergic reactions or to administer emergency medication.
• Participation in any other intervention study at the time of the ORKA study, with the exception of studies on guided early introduction of high-allergenic nutrition.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 12-04-2019
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49735
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7663
CCMO	NL67711.075.18
OMON	NL-OMON49735

Study results