Oral immunotherapy in young children diagnosed with food allergy

Gepubliceerd: 12-04-2019 Laatst bijgewerkt: 15-05-2024

For this feasibility study, no hypothesis have been made.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20790

Bron
NTR

Verkorte titel
ORKA study

Aandoening

Food allergy

Ondersteuning

Primaire sponsor: Deventer Ziekenhuis
Overige ondersteuning: www.dz.nl

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

For this feasibility study, no hypothesis have been made.

Onderzoeksopzet

Evaluation at 6 months

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Deventer ziekenhuis
Ted Klok

+31570535353

Wetenschappelijk

Deventer ziekenhuis
Ted Klok

+31570535353

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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 slgÉ> 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-04-2019
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	12-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49735
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten