An explorative intervention study to investigate the feasibility and safety of oral immunotherapy with different allergens in young children diagnosed with food allergy.

Published: 21-01-2019
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Primary: Is OIT with standard food products safe to perform in children aged 9 to 24 months with a proven food allergy for hen's egg, peanut, cow's milk, cashewnut, hazelnut, walnut and/or one of the more rare allergens (as soy, pits and...

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

Summary

ID

NL-OMON49735

Source
ToetsingOnline

Brief title
Oral immunotherapy in young children diagnosed with food allergy

Condition

- Allergic conditions

Synonym
Food allergy

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: door ziekenhuis zelf

Intervention

Keyword: Anaphylaxis, Food allergy, Immunotherapy, Infants

Outcome measures

Primary outcome

Safety based on the number of anaphylactic reactions that occur within 2 hours after administration of the food product. Feasibility as assessed by both parents and doctors. Effectiveness measured as the number of children with long-term tolerance (SU): a negative provocation test 4 weeks after the discontinuation of the OIT and a problem-free introduction of the food allergen in the diet, and the number of children with remission: a negative food provocation at least 2 years after cessation of OIT, with strict avoidance of the specific food allergen in in the 12 weeks preceding the provocation test.

Secondary outcome

• Number of children with sustained unresponsiveness: a negative food challenge 4 weeks after discontinuation of OIT.

• Number of children with a problem-free introduction of the food allergen in the diet 6 months after discontinuation of the OIT.

• Number of children with food allergy remission: a negative food provocation at least 2 years after cessation of OIT, with strict avoidance of the specific food allergen in the 12 weeks preceding the food provocation

Study description

Background summary

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 hardly 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.

Study objective

Primary: Is OIT with standard food products safe to perform in children aged 9 to 24 months with a proven food allergy for hen's egg, peanut, cow's milk, cashewnut, hazelnut, walnut and/or one of the more rare allergens (as soy, pits and seeds (sesame seed, pine nut and wheat)? And what is the feasibility of OIT with a low daily dose of a standard food product in these children?
Secondary: Can OIT induce long-term tolerance (SU) in children with a proven food allergy in the age of 9 to 24 months (compared to a control group)? And does tolerance persist in the years following therapy?

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.

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 about 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. If this provocation test is negative then a follow-up provocation test takes place 2 years after discontinuation of OIT after 12 weeks of strict avoidance of the specific allergen

Study burden and risks

In every child with a food allergy, different tests and / or a food provocation takes place. The extra burden of this study is: a maximum of 3 blood tests, 2

visits to the policlinic and 2-15 visits to the clinic for provocation or increasing the dose. Parents will complete questionnaires and track the daily administration of the food product in an app.
Patients have an extra risk of an allergic reaction, which is usually mild in nature, but a serious allergic reaction with, for example, bronchoconstriction is not excluded.
The advantage of participating in the study is the possibility of a definitive cure for an otherwise lifelong existing food allergy. Parents often find this possibility more important than the burden of hospital visits, extra blood collection and the risk of allergic reactions. In addition to the individual benefit of participating in the study, the study contributes to the development of a treatment perspective for other children with a food allergy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)

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 sIgE> 0.35kU / L) for chicken egg, peanut, cow's milk, cashewnut, hazelnut, walnut and/or one of the more rare allergens (as soja, pits and seeds (sesameseed and pine nut) and 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 toddler asthma and / or frequent exacerbations (viral wheezing) defined as toddlers who have been 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-randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2019
Enrollment:	183
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	21-01-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-09-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-05-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-02-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-10-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	19-02-2025
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 20790
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67711.075.18