A randomized controlled trial to investigate the (cost)effectiveness of oral immunotherapy with different allergens in young children with an established food allergy.

Published: 22-11-2022
Last updated: 19-08-2024

What is the clinical- and cost-effectiveness of early low-dose oral immunotherapy aimed at long-term tolerance induction in children under the age of 30 months with an established food allergy compared to routine care?What is the effect of early low...

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

Summary

ID

NL-OMON51688

Source
ToetsingOnline

Brief title
A RCT on oral immunotherapy in young children with food allergy.

Condition

- Allergic conditions

Synonym
Food allergie

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: Zorginstituut Nederland

Intervention

Keyword: Anaphylaxis, Food allergy, Infants, Immunotherapy

Outcome measures

Primary outcome

Sustained unresponsiveness, defined as passing an exit oral food challenge at 4 weeks after discontinuation of the 12 months oral immunotherapy, and uncomplicated consumption of a full dose of the specific food at home, after 6 months unrestricted introduction of the specific food into the diet.

Secondary outcome

Quality of life, costs/impact of food allergy and treatment, immunological parameters (blood tests), adherence to treatment.

Study description

Background summary

Recent studies suggest that oral immunotherapy is associated with long-term tolerance development in food allergic children, but only when started early in life. Currently, no randomized controlled trials are performed for different kinds of food allergies in these young children.
Hypothesis: Early low-dose oral immunotherapy in young children with an established food allergy will induce long-term tolerance within one year in at least 50% more children compared to the percentage of children who achieve spontaneous tolerance in the routine care group (strict avoidance of the allergen).

Study objective

What is the clinical- and cost-effectiveness of early low-dose oral

immunotherapy aimed at long-term tolerance induction in children under the age of 30 months with an established food allergy compared to routine care?
What is the effect of early low-dose oral immunotherapy in children under the age of 30 months with an established food allergy on (allergy specific) quality of life of parents and children compared to routine care?

Study design

Randomized controlled superiority trial

Intervention

1-year low-dose oral immunotherapy (daily 300 mg allergenic protein) compared to strict avoidance in the control group.

Study burden and risks

Burden: in all children participating in the study, oral food challenges are performed, and two blood samples are obtained (both will completely or partially be part of routine diagnostic allergy care). Parents have to fill in 4 questionnaires each 6 months. Children whose allergy is assigned to the intervention group, have to visit the hospital for an additional 1 to 6 times during the build-up phase of the treatment and an additional blood sample is obtained after 6 months of therapy. Parents have to take care of daily ingestion of the allergenic food by their child at home.
Risks: the main risk of oral immunotherapy is the occurrence of allergic side-effects. Because a food allergy is definition characterized by an allergic reaction in case of an accidental ingestion, parents have to be prepared for the risk of allergic reactions already. Inducing long-term tolerance, the main goal of this treatment, would prevent a life-long risk of allergic reactions caused by accidental ingestions.
Group relatedness: current scientific knowledge suggests that only in food-allergic infants oral immunotherapy may be associated with long-term tolerance in contradiction with school-aged children.

Contacts

Public
Deventer Ziekenhuis

Nico Bolkensteinlaan 75
Deventer 7416 SE
NL
Scientific

Deventer Ziekenhuis

Nico Bolkensteinlaan 75
Deventer 7416 SE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

- 9 to 30 months of age at inclusion.
- an IgE-mediated food allergy to peanut, cashew, hazelnut, walnut, cow*s milk and/or hen*s egg as proven by sensitization to the specific allergen (sIgE > 0.35kU/l) and a positive oral food challenge.
- The fore-mentioned allergens are introduced into the diet of the child (the child is tolerant for the specific allergen(s)), or the child is diagnosed with a food allergy for the specific allergen(s).
- Informed consent is given by parent(s) or guardian(s).

Exclusion criteria

- (suspected) eosinophilic oesophagitis
- uncontrolled asthma/ viral wheeze.
- the inability of parents to follow instructions, recognize allergic reactions or administer emergency medication.
- participation in any other intervention study at the time of the OIT study, with the exception of studies on guided early introduction of highly allergenic foods.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-01-2023
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	22-11-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-12-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-01-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-12-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	24-05-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL81774.075.22