Food allergy diagnosis and intervention to improve children's health

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Primary Objective: - Evaluate changes in immune response during oral immunotherapy with either peanut or baked milk in children with a mild peanut or cow*s milk allergySecondary Objective: - Compare the immunological changes at baseline and over...

Ethical review	Approved WMO
Status	Pending
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON57337

Source
ToetsingOnline

Brief title
FAITH study

Condition

- Allergic conditions

Synonym
food allergy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: basophils and memory B cells, cow□s milk allergy, oral immunotherapy, peanut allergy

Outcome measures

Primary outcome

The main study parameters are serum antibodies (IgE and IgG) and blood immune cells (especially basophils, B cells, T cells and subsets therein) with specificity to the food component for which a subject is allergic.

The primary endpoint is to evaluate early (at 4 months) and late (at 12 months) changes in immune response during oral immunotherapy with either peanut or baked milk in children with a mild peanut or cow's milk allergy.

Secondary outcome

Comparison of immunological changes at baseline and over time between mild peanut allergic children treated with peanut snacks versus severe peanut allergic children remaining on a peanut free diet, as well as mild cow*s milk allergic children treated with baked milk versus severe cow*s milk allergic children remaining on a cow*s milk free diet.

Study description

Background summary

Affecting 6-8% of children, food allergies can be life-threatening, and especially common sources, such as peanut and cow*s milk, are extremely difficult to avoid. In recent years, hospital admissions due to food anaphylaxis have increased significantly from 1.2 to 4.0 per 100,000 people per year. The main increase was seen in children <15 years of age with an annual increase of 6.6 % from 2.1 to 9.2 admissions per 100,000. In children with fatal anaphylaxis, milk was the causative allergen in 26% and peanut in 14% of

cases. The natural course of disease in children with peanut and cow*s milk allergy differs. About 20% of young children with a peanut allergy will outgrow this allergy by early adulthood. In children with an IgE-mediated cow*s milk allergy about 50% will develop tolerance at the age of 5 years and 75% is tolerant by early adolescence.

At present, there is no available, reimbursed treatment for food allergy in the Netherlands. Therefore, there is a large unmet need for a safe treatment intervention that increases tolerance levels to ensure that affected children do not experience severe reactions to accidental exposure.
Oral immunotherapy (OIT) with food allergens is not a common treatment yet for children with food allergies. Peanut allergic children treated with OIT show good results regarding desensitization (no reaction while on daily peanut intake); however, sustained unresponsiveness (the ability to still tolerate peanut after a short period of avoidance) is less successful. Sustained unresponsiveness is more successful in younger children and in children with lower specific IgE to peanut. All studies investigating OIT are performed in severe peanut allergic children, diagnosed using an oral food challenge (OFC) test. However, not much is known about OIT in peanut allergic children with a higher threshold to peanut. Oral food challenges are performed in the diagnostic work-up to evaluate the threshold and the severity of the reaction. At present, in the Erasmus MC-Sophia Children*s hospital / KinderHaven, children with a mild allergic reaction to peanut after a relatively high threshold (>2 peanuts) are offered to either avoid peanut or to introduce small amounts of peanut according an introduction scheme with peanut flips (see Appendix A). In this group of peanut allergic children, controlled, daily intake of peanut snacks has shown promising results for tolerability.
Cow*s milk allergic children can benefit from introduction of baked milk (milk in baked form, e.g. in cookies). Baked milk is less allergenic than pure dairy and can be tolerated by approximately 70% of cow*s milk allergic children, advancing tolerance to pure milk. Children with severe IgE-mediated symptoms to dairy will usually first have an OFC with baked milk. If baked milk is tolerated, it can be introduced on a daily base in their diet to improve tolerance for cow*s milk. However, not all children are tolerant to baked milk. In these cases the child needs to maintain a strict cow*s milk free diet.

The immunological mechanisms behind allergen immunotherapy or food introduction are not completely understood, and there are no immunological markers to predict outcome. Using state-of-art allergen-specific immunological measurements, we have previously identified new immunological markers that change early during successful immunotherapy for ryegrass pollen and bee venom. In the current study, we will apply these measurements to investigate the immune system in children with a peanut or cow*s milk allergy (as these have distinct natural courses of disease) and evaluate immunological changes during intervention through daily, controlled food intake in order to increase tolerance.

Study objective

Primary Objective:
- Evaluate changes in immune response during oral immunotherapy with either peanut or baked milk in children with a mild peanut or cow*s milk allergy

Secondary Objective:
- Compare the immunological changes at baseline and over time between mild peanut allergic children treated with peanut snacks versus severe peanut allergic children remaining on a peanut free diet, as well as mild cow*s milk allergic children treated with baked milk versus severe cow*s milk allergic children remaining on a cow*s milk free diet.

Study design

This is a prospective single-center observational research study to investigate immunological changes in mild and severe peanut and cow*s milk allergic children who are on different diets.

Peanut allergic children: According to regular care (as described in the introduction), children with a peanut allergy undergo an OFC with peanut to evaluate the threshold and severity of their reaction to peanut. In case of a mild reaction towards a relatively large dose of peanut (>= 300 mg peanut protein which is equal to 2 peanuts), patient and parents are informed to start introduction of peanut (according to a specific scheme) mild peanut allergy group, n=30). If they had a reaction < 2 peanuts or if they have had a severe reaction after a larger dose (treatment needed with adrenaline) they remain on a diet free of peanut (severe peanut allergy group, n=15).

Cow*s milk allergic children: According to regular care (as described in the introduction) children with a cow*s milk allergy undergo an OFC with baked milk to evaluate the threshold and severity to baked milk. If they tolerate baked milk or have a mild reaction after a relatively large amount of baked milk (>= 300 mg cow*s milk protein), patients and parents are advised to introduce baked milk in the diet (according to an introduction scheme of baked milk) (mild cow*s milk allergy group, n=30). In case of a reaction < 300 mg of cow's milk protein or if they have had a severe reaction after a larger dose (treatment needed with adrenaline) they remain on a strict cow*s milk free diet (severe cow's milk allergy group, n=15).

Following the diagnosis and treatment decisions as described above (regular patient care), all children (mild and severe allergic children) will be asked to participate in this prospective study in order to evaluate immunological changes between mild and severe forms of food allergy and the effect of treatment over time. Enrolment in this study will not impact on their treatment nor will it affect treatment decisions. All children will be asked to donate

blood (9-18 mL) before start of the study at t=0 (can be combined with regular diagnostic testing before OFC), and at 4 and 12 months. At 12 months an OFC with either peanut or cow*s milk will be repeated.

Study burden and risks

There is no perceived risk to the participants, investigators or institution. Participants are having an additional 9-18 mL of blood sample taken at 3 time points along with routine care. All blood sampling will follow Good Clinical Practice.
This research will not provide a direct therapeutic benefit to the participant. However, we hope it will contribute by improving diagnosis, monitoring and treatment of allergies in the future. The project will aid in identifying potential biomarkers of allergy and treatment options.
This project will have positive impacts in the field of Allergy by potentially improving patient diagnosis and treatment.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 40 40
Rotterdam 3015GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 40 40
Rotterdam 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Aged 4-18 years
Allergic to peanut diagnosed with a peanut OFC
OR
Allergic to cow*s milk diagnosed with a baked milk OFC
Provided written informed consent

Exclusion criteria

Under systemic immunosuppressive treatment
History of hematological malignancy, immunodeficiency or autoimmune disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	90
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	10-03-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL88123.078.24