

# Verband tussen dieetsamenstelling micoörganismen in het maagdarmkanaal en de gevoeligheid voor pinda kinderen met een pinda allergie. Een pilot studie

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON24764

### Source

Nationaal Trial Register

### Brief title

DIGESTIV pilot study

### Health condition

Children with confirmed or suspect peanut allergy in whom an oral food challenge with peanut is performed

## Sponsors and support

**Primary sponsor:** OLVG

**Source(s) of monetary or material Support:** OLVG

## Intervention

## Outcome measures

### Primary outcome

Relationship between composition of the diet, composition of the microbiome and the reactive dose (threshold levels) in positive Open peanut challenge or DBPCFC with peanut.

## Secondary outcome

In children, while on a peanut free diet, with a negative or positive peanut challenge:

1. Intake of foods, food groups, macro- and micronutrients while on peanut free diet
2. Quality of life scores
3. Amount of food-derived microbes in diet

In children, while on a peanut free diet, with a positive peanut challenge

4. Microbiome characterization of oral cavity
5. Microbiome characterization of the gut.

## Study description

### Background summary

Peanut allergy is a common disease, may be lifelong and may be severe. Like other allergic diseases, the prevalence of peanut allergy has increased during the last few decades. Food allergy develops as a consequence of a failure in oral tolerance, which is a default immune response by the gut-associated lymphoid tissues to ingested antigens, which is modified by the gut microbiota.

Inter-individual thresholds in peanut allergic children widely differ. Thresholds can be determined in open or double-blind, placebo-controlled oral food challenge tests (DBPCFC), ranging from traces to grams of peanut protein. It is poorly understood how these differences in sensitivity (threshold levels) between individuals can be explained. One possible explanation is a disturbed intestinal barrier function, allowing enhanced uptake of allergens where they may activate the immune system, leading to severe chronic inflammation.

The composition of the diet may have important effects on the immune response in food allergy as related to mucosal integrity and inflammation, either inducing a tolerogenic or allergy promoting effect and consequently impacting the sensitivity of patients. Additionally, we hypothesize that the total amount and diversity of non-pathogenic food-derived microbes induce probiotic-like effects by interacting with the gastro-intestinal microbiome and the immune system and promote the induction of tolerance, which already starts in the mouth.

The primary aim of this pilot study is to test the feasibility and strength of the relationship

between dietary composition, (foods, macro- and micronutrients and estimated amounts of food-derived microbes), gut and oral microbial composition and threshold levels (reactive dose) in peanut allergic children, as established by positive open and double-blind, placebo-controlled food challenges (DBPCFC) with peanut.

The secondary aim is to compare the composition of the diet of children being on a peanut free diet, prior to oral food challenge, with the recommended daily allowances and the average intake by Dutch children as measured by the National Food Consumption Survey.

## Methods

In this multicenter, cross-sectional, pilot study, 50 Children (0-18 years) in whom consecutively Open peanut challenges or DBPCFCs with peanut are performed for routine diagnostic care between 1 February and 30 September 2017 will be included. At baseline, the composition of the diet, including the estimated dietary microbial load for lactobacillae, spoilers and yeasts/fungi, is investigated by 3-day food diaries which are analysed electronically (Compl-eat), quality of life using validated questionnaires, microbiota composition of the gut and mouth by stool and saliva samples respectively using standard IS-pro procedures.

Cox regression (Survival analyses/Hazard Ratios) and/or multivariate regression analysis will be applied to study the relationship between nutritional and/or microbial variables and threshold doses. Also the relationship between Quality of life and threshold doses will be studied.

## Study objective

Peanut allergy is a common disease, may be lifelong and may be severe. Like other allergic diseases, the prevalence of peanut allergy has increased during the last few decades. Food allergy develops as a consequence of a failure in oral tolerance, which is a default immune response by the gut-associated lymphoid tissues to ingested antigens that is modified by the gut microbiota.

Inter-individual thresholds in peanut allergic children widely differ. Thresholds can be determined in open or double-blind, placebo-controlled oral food challenge tests (DBPCFC), ranging from traces to grams of peanut protein. It is poorly understood how these differences in sensitivity (threshold levels) between individuals can be explained. One possible explanation is a disturbed intestinal barrier function, allowing enhanced uptake of allergens where they may activate the immune system leading to severe chronic inflammation.

It is now increasingly recognized that foods and nutrients play an important role in the maintenance or disruption of the mucosal integrity and the process of inflammation through:

a. local effects on epithelial integrity and mucosal epithelium and mucosal immune system of the gastro-intestinal tract,

b. influencing the composition of the gut microbiota which in its turn has immunomodulatory properties (20, 27) and is shown to be different between allergic and non-allergic individuals (28-33)

c. systemic effects on the immune system through micronutrients.

Thus, the composition of the diet may have important effects on the immune response in food allergy as related to mucosal integrity and inflammation, either inducing a tolerogenic or allergy promoting effect and consequently impacting the sensitivity in patients.

Additionally, we hypothesize that the total amount and diversity of non-pathogenic food-derived microbes induce probiotic-like effects by interacting with the gastro-intestinal microbiome and the immune system and promote the induction of tolerance, which already starts in the mouth.

The primary aim of this pilot study is to test the feasibility and strength of the relationship between dietary composition, (foods, macro- and micronutrients and amount of food-derived microbes), gut and oral microbial composition and threshold levels (reactive dose) in peanut allergic children, as established by positive open and double-blind, placebo-controlled food challenges (DBPCFC) with peanut.

The secondary aim is to compare the composition of the diet of children being on a peanut free diet, prior to oral food challenge, with the recommended daily allowances and the average intake by Dutch children as measured by the National Food Consumption Survey.

## **Study design**

Collection of baseline variables

- Patient characteristics (routine measurement), including ethnic background
- Atopic comorbidity, other food allergies
- sIgE/SPT peanut (routine diagnostic measurement)
- 3-day food diaries (in week prior to oral food challenge)
- Quality of Life questionnaire (in week prior to oral food challenge)
- Stool sample (1 - 2 days prior to oral food challenge)
- Saliva sample (just prior to oral food challenge)

## Intervention

none

## Contacts

### Public

PO Box 95500, Department of Paediatrics

B.J. Vlieg-Boerstra  
Amsterdam 1090 HM  
The Netherlands  
+31620965612

### Scientific

PO Box 95500, Department of Paediatrics

B.J. Vlieg-Boerstra  
Amsterdam 1090 HM  
The Netherlands  
+31620965612

## Eligibility criteria

### Inclusion criteria

Inclusion criteria for dietary analysis and quality of life scores

- All children eligible for an open or double-blind peanut challenge.
- Presence of IgE to peanut  $\geq 0.35$  kU/l.

Inclusion criteria for microbial characterization

- Children with a positive open or double-blind, placebo-controlled challenge with peanut
- Presence of IgE to peanut  $\geq 0.35$  kU/l.

## Exclusion criteria

### Exclusion criteria

- Children not eligible for peanut challenge, according to protocol
- Absence of IgE to peanut
- A negative peanut challenge
- Antibiotic use shorter than 3 months prior to the oral food challenge

## Study design

### Design

Study type: Observational non invasive

Intervention model: Other

**Control:** N/A , unknown

### Recruitment

NL  
Recruitment status: Recruitment stopped

Start date (anticipated): 01-02-2017

Enrollment: 60

Type: Actual

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Not applicable

Application type: Not applicable

## 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
NTR-new	NL6188
NTR-old	NTR6509
Other	ACWO OLVG : WO 17.000 oost/west

## Study results