

# Peanut sensitization, the relationship with peanut-related symptoms and asthma in children

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- To determine the association between peanut sensitization and food related physical symptoms  
- To determine the association between peanut sensitization and the severity of asthma in children

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Allergic conditions
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON35756

### Source

ToetsingOnline

### Brief title

Peanut sensitization, peanut-related symptoms and asthma

### Condition

- Allergic conditions
- Bronchial disorders (excl neoplasms)

### Synonym

hypersensitivity reaction, intolerance

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Isala Klinieken

**Source(s) of monetary or material Support:** eigen middelen

## Intervention

**Keyword:** Asthma, Food-related symptoms, Peanut, Sensitization

## Outcome measures

### Primary outcome

The association between peanut sensitization and food related symptoms in children

- The absence of peanut allergy, as determined by a questionnaire and interview
- The level of peanut sensitization, as determined by laboratory tested IgE
- The presence of sensitization of allergens beside peanuts

### Secondary outcome

The association between peanut sensitization and asthma in children

- The percentage of children with a combination peanut sensitization and asthma
- The severity of the asthma

## Study description

### Background summary

The diagnosis of food allergy is complicated. The patient's medical history as obtained by a relative is often unreliable and laboratory tests can only show sensitization. While double-blind placebo-controlled food challenges remain the "gold standard" in food allergy diagnosis, logistic and practical difficulties make it less applicable for daily practice. As a result, the test is not used often, possibly causing many false positive diagnoses of food allergy in children, unnecessary elimination diets and their consequences. The exact association between food related symptoms, sensitization and food allergy is currently unknown.

Food allergy is part of the atopic syndrome. It is known that children with asthma and food allergy have an increased risk of developing an anaphylactic reaction after exposure to the food allergen. Therefore, identification of

children with a combination of food allergy and (unknown) asthma is important to counsel parents on the risk of developing anaphylaxis.

The aim of our study is to improve our ability to interpret the laboratory results of food sensitization in a clinical situation. This will help us in the future to determine which children will develop food related physical symptoms. Further, a second aim of the study is to determine the association between peanut sensitization, peanut allergy and the severity of asthma.

### **Study objective**

- To determine the association between peanut sensitization and food related physical symptoms
- To determine the association between peanut sensitization and the severity of asthma in children

### **Study design**

Prospective cohort

### **Intervention**

The parents of the participating children will fill out two validated questionnaires. The first is regarding their child's exposure to peanut and his food related physical symptoms. The second is about asthma related physical symptoms. Based on the first questionnaire, we will decide if there is a possibility of a true peanut allergy or not. In case this could be present, they and their child (if >6 years) are invited to visit the out-patient clinic of the Amalia pediatric department for an interview. During this interview the child's exposure to peanuts and its symptoms will be discussed in more detail. If asthma-related symptoms exist, this will also be discussed in more detail. Children six years of age or older will participate in a lung function test as well.

If there still is suspicion of true peanut allergy after this interview and the child is four years of age or older, parents will be offered for their child to participate in a double-blind placebo-controlled food challenge to diagnose the existence of the allergy.

This is not a component of this study, it will be regular patient care.

### **Study burden and risks**

A disadvantage of participation will be the time involved. The participants and/or their parents will complete a questionnaire, and will be seen at the pediatrics department up to 1 time. This will be an interview and a lung

function test.

However, as stated before, there will be a possibility to clarify their peanut sensibility and possibly their asthma-related symptoms.

This study will investigate the peanut sensitization in children. We are specifically interested in the symptoms of peanut-allergy in children. We can not extrapolate the symptoms of adults to children.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

## Inclusion criteria

All children with a positive IgE-test for peanut-allergens, as tested by the clinical laboratory of the Isala Klinieken, between Januari 2004 and May 2010 and aged 18 years or younger at time of the IgE test.

## Exclusion criteria

serious comorbidity

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 20-06-2011

Enrollment: 425

Type: Actual

## Ethics review

Approved WMO

Date: 16-06-2011

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

## 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	NL35883.075.11