

# Clinical follow up of EuroPrevall birth cohorts

## A part of Integrated approaches to Food Allergen and Allergy Risk Management consortium study

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To trace new onset of food allergy and clinical evolution of already established food allergy, determining frequencies and patterns of tolerance development. Influence of environmental and behavioural factors will be investigated.

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

### Summary

#### ID

NL-OMON40775

#### Source

ToetsingOnline

#### Brief title

Clinical follow up of EuroPrevall birth cohort as part of iFaam study

#### Condition

- Allergic conditions

#### Synonym

Food Allergy

#### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Europese Unie

## Intervention

**Keyword:** Double blind placebo controlled food challenges, Follow up birth cohort up to 5-10 years of age, Prevalence Allergic sensitization, Prevalence Food allergy

## Outcome measures

### Primary outcome

Prevalence of food allergy and influences on food allergy in this group up to the age of 5-10.

### Secondary outcome

Astma, allergic rhinitis and eczema in this group

## Study description

### Background summary

The EuroPrevall birth cohort enrolled 12049 newborns between 2005 and 2010 in nine countries and traced development of food allergy over the first 30 months of life. This follow up study aims to follow up all the children at 5-10 years of age between 2014 and 2016.

Main goals is to know the Prevalence of food allergy and other allergies in this group.

### Study objective

To trace new onset of food allergy and clinical evolution of already established food allergy, determining frequencies and patterns of tolerance development. Influence of environmental and behavioural factors will be investigated.

### Study design

Alle 976 participants will be asked for participation in this follow up study. In Europe all 12049 children will be contacted for participation.

3 levels of the study:

Level 1: online questionnaire for parents

Level 2: clinical investigation in hospital with blood drawing and skin prick test

Level 3: Suspicion of food allergy is further evaluated with standardized double-blind placebo-controlled food challenges in the hospital.

### **Study burden and risks**

Depends on which level of participation

level 1: no burden for child, only time of parents for online questionnaire

level 2: low burden of blood drawing and skin prick test. Lidocaine spray will be sprayed on skin before blood drawing for more comfort for child.

level 3: 2 days a couple of hours in hospital for food challenge

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Children (2-11 years)

## Inclusion criteria

All participants of the birth cohort of EuroPrevall will be asked to participate in this follow up study

## Exclusion criteria

no new informed consent for this follow up study

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 25-03-2015

Enrollment: 976

Type: Actual

## Ethics review

Approved WMO

Date: 06-06-2014

Application type: First submission

Review commission: METC Amsterdam UMC

## 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	NL48279.018.14