

# PIAMA (Prevention and Incidence of Asthma and Mite Allergy) 11 year investigation

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The aim of the extended follow-up of the PIAMA cohort is: To investigate changes during the ages of 8 to 11-12 years in lifestyle, nutrition, physical activity and health related attitude and behavior that are relevant to the development of asthma,...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Lower respiratory tract disorders (excl obstruction and infection)
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON31578

### Source

ToetsingOnline

### Brief title

PIAMA

### Condition

- Lower respiratory tract disorders (excl obstruction and infection)
- Epidermal and dermal conditions
- Environmental issues

### Synonym

asthma, eczema

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universiteit Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Allergy, Asthma, Environment, Lifestyle

## Outcome measures

### Primary outcome

astma

hay fever

eczema

lung function

IgE

NO in exhaled air

serum cholesterol

HbA1C

HDL cholesterol

glucose

cortisol in saliva

### Secondary outcome

not relevant

## Study description

### Background summary

The PIAMA study (Prevention and Incidence of Asthma and Mite Allergy) is a combination of an intervention trial and a natural history study of the development of asthma and allergic disease in childhood. The study has been ongoing since 1996. The first eight years of follow up is now completed. For

the further follow-up of this cohort we will broaden the focus from allergy and asthma to early development of other chronic diseases as well. The aim of the next phase is to investigate changes between the ages of 8 to 13-14 years in lifestyle, nutrition, physical activity and health related attitudes and behavior that are relevant to the development of asthma and other chronic diseases.

## **Study objective**

The aim of the extended follow-up of the PIAMA cohort is:

To investigate changes during the ages of 8 to 11-12 years in lifestyle, nutrition, physical activity and health related attitude and behavior that are relevant to the development of asthma, allergy and other chronic diseases. Health outcomes that will be studied at the age of 11-12 include asthma, other allergic diseases (such as eczema and hay fever) and overweight. We will collect important information on the development and early stages of cardiovascular disease and diabetes from early markers and we will include measurements of blood pressure, blood cholesterol, glucose and HbA1c levels in blood and cortisol levels in saliva. And, we will investigate aspects of lifestyle that are known to be associated with the development of cardiovascular disease and diabetes.

## **Study design**

The PIAMA study \*Prevention and Incidence of Asthma and Mite Allergy\* is a prospective birth cohort study among children recruited before birth (3 months of gestational age). At age 11-12 we plan to collect data on clinical endpoints in addition to the data that will be collected through questionnaires. At age 11-12, changes in lifestyle and behavior will influence the development of body weight and chronic diseases.

Through a physical examination at age 11, we propose to collect:

A. Serum and plasma to measure

- total IgE and specific IgE to common food allergens (a.o. milk protein and hen's egg) and inhalant allergens (mite, cat, dog, alternaria, grasses, trees)
- glucose, HbA1c, total cholesterol and HDL cholesterol.

B. Lung function measurements

- forced expiratory spirometry including peak flow and FEV1
- nitric oxide (NO) in exhaled air as a marker of airway inflammation (as at age 4 and 8 years)

C. Anthropometry (mostly as at age 4 and 8 years)

- Height
- Weight
- Sitting height
- Waist circumference
- Hip circumference

D. Measurement of blood pressure

E. Collection of saliva for cortisol determination

### **Study burden and risks**

The burden to the participants is small: participation for up to 60 minutes in simple diagnostic tests and one venous blood sample in the own home. The risk involved in blood sampling by trained personnel is negligible.

## **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)

Children (2-11 years)

### **Inclusion criteria**

nvt

## Exclusion criteria

nvt

## 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): 17-09-2008

Enrollment: 3500

Type: Actual

## Ethics review

Approved WMO

Date: 20-05-2008

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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	NL19955.041.07