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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	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

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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