

PIAMA (Prevention and Incidence of Asthma and Mite Allergy) project, 15/16 year investigation

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The aim of the current proposal is to investigate the effects of changes in lifestyle, food intake, physical activity and health related behavior during adolescence on development of asthma, allergy and other chronic diseases. Health outcomes that...

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-OMON37390

Source

ToetsingOnline

Brief title

PIAMA 15/16

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, EU FP7 MEDALL project

Intervention

Keyword: Allergy, Asthma, Environment, Lifestyle

Outcome measures

Primary outcome

asthma

hay fever

eczema

lung function

IgE

NO in exhaled air

serum cholesterol

HDL cholesterol

HbA1c

cortisol in sputum

Secondary outcome

indicators of chronic diseases: overweight, cholesterol

Study description

Background summary

In PIAMA we study asthma and allergy and early development of other chronic diseases in children. The study started in 1996, children were included before they were born. In the course of the study they have been approached for inventarisations, usually through questionnaires but a couple of times through a medical examination. In the current phase we want to study the influence of

changes in lifestyle, food intake, physical activity and health related behavior on asthma, allergy and other chronic diseases.

Study objective

The aim of the current proposal is to investigate the effects of changes in lifestyle, food intake, physical activity and health related behavior during adolescence on development of asthma, allergy and other chronic diseases. Health outcomes that will be studied in the age of 15/16 years are asthma, other allergic diseases (like 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 and HbA1C levels in blood and cortisol levels in saliva. And, we will investigate the genetic determinants, gene-environment interactions and the role of epigenetic mechanisms in the development of chronic diseases and how single nucleotide polymorphisms affect gene transcription and epigenetic regulation. We will therefore isolate DNA from peripheral blood and nasal epithelium cells for gene-expression.

Study design

The people still participating in PIAMA (about 3350) will all be invited to participate in a medical examination comparable to examinations they have participated in, before. The examination consists out of anthropometric measures, bloodpressure measurement, determination of exhaled NO, spirometry and hyperreactivity, sampling of sputum, nasal epithelium and blood.

Study burden and risks

Participating in this examination will take at most 2 hours of the participant's time. The tests we will perform are simple and of little impact for the participant. There is little or no risk of complications for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Inclusion criteria

Adolescents aged 15/16 years who are still participating in ongoing PIAMA study

Exclusion criteria

not relevant

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): 22-11-2012
Enrollment: 1500
Type: Actual

Ethics review

Approved WMO
Date: 25-05-2012
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	NL38834.041.12