KOALA Birth Cohort Study: home-visits at age 6-8 years.

Published: 14-07-2008
Last updated: 07-05-2024

To examine the influence of genetic predisposition, genetic factors, infections and lifestyle of mother and child in relation to 1) allergic diseases and childhood astma;2) childhood overweight and obesity; 3) cardiopulmonary fitness and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31560

Source
ToetsingOnline

Brief title
KOALA

Condition

- Other condition
- Allergic conditions
- Bronchial disorders (excl neoplasms)

Synonym
allergy/asthma and overweight/obesity

Health condition

overgewicht/obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Astmafonds;Hartstichting,Friesland Nutrition,Suikerstichting

Intervention

Keyword: allergie, asthma, childhood, overweight

Outcome measures

Primary outcome

During this follow-up main study parameters of allergic diseases will be parentally reported symptoms as assessed by validated questionnaires in the whole study population. Phenotypes of asthma are measured in the child (NO in exhaled air, lung function as assessed by spirometry (baseline and if below a certain thresshold, reversibility of obstruction by response to a bronchodilator), eczema as diagnosed by a trained nurse, in a part of the cohort (n = 1598). Phenotypes of overweight, obesity and related parameters are measured (weight, height, waist circumference, skinfold thickness, blood pressure, body fat composition by bioelectric impedance analysis). Furthermore, the following biosamples will be taken from the child and biobanked: a new faecal sample (to determine the microbial composition); exhaled breath condensate (for future measurement of inflammation markers) and finger prick blood (for measurement of specific IgE against common food and airway allergens, and for future measurement of metabolic parameters). During this period blood pressure measurement will be done twice daily by the parents, using the Omron device for self-measurement.

Baseline lung function tests and body composition will also be measured in

mothers, as well as blood pressure measurements in both parents. These data will be used as a measure for the child's constitution and shared environment.

A subgroup of children will be invited to the hospital (In case of any doubt on the diagnosis of asthma as obtained by the lung function testing during the home-visit combined with reported symptoms). At the hospital a histamine provocation test will be performed to elucidate wether the child has asthma or not (see figures 1 and 2).

Secondary outcome

Not applicable

Study description

Background summary

The prevalence of allergic diseases, asthma, overweight and obesity has rapidly increased during the past decades, especially in western countries and amongst children. Besides genetic susceptibility, lifestyle and environmental factors, such as diminished/altered microbial exposure, play an important role in the etiology of allergies. Feeding and snacking practices and physical activity have also changed and affect the balance between energy intake and expenditure. Asthma is more prevalent in obese children, and this may be due to shared biological, behavioural and environmental factors.
Within the KOALA Birth Cohort Study we have examined the possible role of several lifestyle and environmental factors in the development of eczema, wheeze, allergic sensitisation, overweight and obesity in the first two years of life. Further follow-up will enable us to study the influence of these factors on the development of other allergic diseases, such as childhood asthma, the development of obesity and cardiopulmonary fitness, and cardiovascular and metabolic risk factors for adult pulmonary and cardiovascular diseases.

Study objective

To examine the influence of genetic predisposition, genetic factors, infections

and lifestyle of mother and child in relation to 1) allergic diseases and childhood astma;
2) childhood overweight and obesity; 3) cardiopulmonary fitness and cardiovascular and metabolic parameters as risk factors for adult pulmonary and cardiovascular diseases.

Study design

The KOALA Birth Cohort Study is a prospective observational birth cohort study.

This application addresses further follow-up of children participating in the KOALA Birth Cohort Study, a prospective birth cohort.

Intervention

Although the study design is an observational cohort study, the administration of salbutamol to measure reversibility of bronchial obstruction can be seen as a non-therapeutic intervention.
During the home-visit baseline lung function will be measured, subsequently 3 pufs of salbutamol 200 micrograms/puf aerosol will be administered. 15 minutes after administration of the salbutamol lung function will be measured again to determine the reversibility of obstruction.

Study burden and risks

The burden for the parents is to schedule an appointment with the research team for a home visit and to prepare the child; to schedule and perform self-measurements of blood pressure in the morning and evening for 3 days; to collect stool samples; for those children who use inhalant therapy for asthma, to consult the study physician (a paediatric pulmonologist) if needed and to coach the child to pause medication, and for the children participating with physical activity measurements, to help the children wear the accelerometer, and to return the devices to the team at a second home visit. The parents need not record blood pressure and physical activity measurements, since the devices have an electronic memory.
The burden for the child is to cooperate with the measurements (blood measurements twice daily for 3 days) and to wear the accelerometer for 5 days (if selected).
There is a small risk that devices are lost are damaged during use, but the participants are waived for loss or damage.

Participants using bronchodilating medication for asthma complaints are asked to pause inhalant therapy. There is a small risk that airway complaints increase, in which case the child and parents are instructed to restart the therapy.

Risk of blood sampling are small and contained by adherence to the appropriate protocols for infection prevention. Pain by venopunction is limited by the use of a topical anaesthetic cream (EMLA).

Only a subgroup of children will be invited to the hospital (in case of any doubt on the diagnosis asthma based on the lung function testing and reported symptoms during the home-visit). At the hospital a histamine provocation test will be performed. This test is used in the clinic daily and in almost all patients with chronic pulmonary diseases. The histamine provocation test has been examined and validated many times and research has shown that this test can be used safely in this specific age category (6-8 years old children).

Benefits are limited to reporting of immediate measurements where clear reference values exist (lung function, NO and blood pressure) and occasional case finding and advice to consult a physician when extreme measurement values are found (blood pressure above*systolic and ..diastolic, previously undiagnosed asthma when aplying to the ATS/ERS criteria). Measurements where no validated reference values exist or without therapeutic consequences are not communicated to the parents, unless they ask explicitly for it.
Children receive a little gift (color plate, toy). Many parents have shown interest in the scientific results of the KOALA study so far, indicating that many feel related to the KOALA study as a group.

Contacts

Public
Universiteit Maastricht

P. Debyeplein 1
6200 MD Maastricht
Nederland
Scientific
Universiteit Maastricht

P. Debyeplein 1
6200 MD Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for the 6-8 years follow-up is active membership of the cohort, i.e. all cohort members who have not indicated that they wanted to stop cooperation with further follow-up at the previous occasions when they were asked for informed consent, or on other occasions on their own initiative.

Exclusion criteria

At baseline children with congenital diseases and children born prematurely (< 37 weeks) were excluded from the KOALA study.
All children participating in the KOALA study who have been selected for the present follow-up (n = 1598) and their parents are part of the study population.
The total study population thus exists of 4794 (1598 x 3) subjects
However, some children will not take part at al measurements because of contra-indications:;1) The Body fat composition by bioelectrical impedance measurement will not be measured in participants with an electronic implant such as pacemaker for reasons of safety. 2) Contraindications for histamine challenge testing (only in a small subgroup) are:;- Heart diseases
- Other pulmonary diseases than asthma
- Chronic inflammatory systemic diseases
- Not being able to perform lung function testing
- Use of non-selective beta-blockers
- Use of cholinesterase inhibitors
- clinically/pulmonal unstable (e.g. recent exacerbation, infection of upper airways, fever)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2008
Enrollment:	4794
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Salbutamol CFK-vrije Inhalator, aërosol, suspensie, 100 microgram per dosis
Generic name:	Salbutamol
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	14-07-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2008-001540-39-NL
CCMO	NL21278.000.08