The present proposal contains three separate research questions with a different background that both will be an extension of the Wheezing Illnesses Study Leidsche Rijn (WHISTLER). Study 1: The relations between early childhood obesity and arterial disease. Study 2: Low lung function in early childhood: nature or nurture? Study 3: The relation between Diabetes type I during pregnancy and vascular characteristics in the offspring.

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Study 1: The purpose of this study is to gain more insight in the characteristics that are related to vascular damage at a young age, and particularly to detect if obesity is related to vascular damage (and thus the risk of cardiovascular disease in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40078

Source
ToetsingOnline

Brief title
WHISTLER/ Cardio

Condition

- Other condition
- Bronchial disorders (excl neoplasms)

Synonym
Study 1 and 3: cardiovascular diseases. Study 2: asthma.

Health condition

cardiovasculaire ziekten en overgewicht

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: asthma, endothelial dysfunction, lungfunction in infants, overweight in children

Outcome measures

Primary outcome

The primary measured study parameters include obesity related measurements

which comprises of anthropometry (body weight, height) and collection of

nutritional data. Sonographic abdominal fat will be measured using ultrasound.

The vascular conditions will be determined distension and intima-media

thickness of the carotid artery as marker of preclinical atherosclerosis,

measured using ultrasound. Furthermore blood pressure will be measured.

To gain information about the respiratory system we will re-assess lung

function (MicroRint and flow-volume measurements) and measure Nitric Oxide in exhaled air. Current clinical status will be obtained.

Primary outcome in study 3 are the vascular parameters: carotid intima media thickness and vascular stiffness.

Secondary outcome

None

Study description

Background summary

Study 1: The prevalence of childhood overweight and obesity in the Western population has reached epidemic proportions and is continuing to increase. In addition, the likelihood that an obese child will remain obese into adulthood is high. The increase in obesity prevalence, particularly among younger age groups, is likely to have long-term implications for cardiovascular disease in the years to come. The age at which excess weight begins to exert its toll on the cardiovascular system is still unknown, as is the exact mechanism through which cardiovascular damage is accomplished. Obesity might adversely affect cardiovascular health through associations with dyslipidemia, inflammation and hypertension. Obesity might also impair vascular function by vasoactive compounds such as leptin, produced by adipose tissue.

Study 2: At the age of 10 years children with asthma have worse lung function in comparison to healthy controls and this difference persists until late adulthood (so-called *tracking*). Until now, it is unclear whether this poor lung function is due to decreased function from birth (i.e. probably *nature*-factors play an important role) or to progressive loss of function secondary to chronic inflammation and environmental factors (i.e. predominantly *nurture*-factors are important) at very early age. We hypothesize that in healthy children lung function tracks from birth over the first years of life but that different early mechanical and environmental factors can substantially worsen lung function (*de-tracking*).

Study 3: There is now a growing body of evidence that adult cardiovascular

disease may have its origin in early (fetal) life, when specific insults during development may alter later body composition and metabolism. During diabetic pregnancy, maternal hyperglycaemia induces fetal hyperglycaemia, which in turn makes the developing tissues in the offspring more vulnerable to functional alterations later in life. This may eventually lead to the development of some of the components of the metabolic syndrome, such as obesity, hypertension and impaired glucose tolerance. Therefore, it is important to recognize cardiovascular disease risk factors early in the course of life and even, if possible, already in childhood.

Study objective

Study 1: The purpose of this study is to gain more insight in the characteristics that are related to vascular damage at a young age, and particularly to detect if obesity is related to vascular damage (and thus the risk of cardiovascular disease in later life) in early childhood.

Study 2: The current proposal will answer 3 specific questions in a unique birth cohort setting:
1. To what extent does neonatal lung function determine lung function over the first years of life?
2. Are different asthma-phenotypes (resulting in different periods of lung stress) associated with changes in lung function over the first years of life?
3. Do environmental factors affect development of lung function over the first years of life?

Study 3:To investigate whether children born from mothers with Diabetes type I, are more vulnerable to vascular changes.

Study design

The study that we propose to answer the research questions of parts 1 and 2 is a cross-section among preschool children who took part in a birth cohort. Study 3 is a cross-sectional design.

Study burden and risks

There's no risk for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Four- to six-year-old children who are willing and able to undergo the procedures described in the protocol and who*s parents have given written informed consent.
For study 3, 7 to 10 year olds who are willing and able to undergo the procedures described in the protocol and who's parents have given written informed consent will be invited.

Exclusion criteria

No exclusion criteria. For study 3: children who's mother had Diabetes gravidarum or Diabetes type II during pregnancy will be excluded.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2007
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	16-01-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-11-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-11-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-02-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-11-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	30-08-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-11-2014
Application type:	Amendment
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	NL14617.041.06