Children follow-up study of PCOS women

Published: 13-08-2012
Last updated: 26-04-2024

Primary objectives of the pilot study• To determine childhood cardiovascular health in offspring of PCOS mothers and to compare it with children from non-PCOS mothers.Secondary objectives of the pilot study• To compare cardiovascular risk factors...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON39806

Source
ToetsingOnline

Brief title
CHOPS

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Respiratory disorders NEC
- Vascular hypertensive disorders

Synonym
PCOS, polycystic ovary syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Child Health Grant 1 in het kader van speerpunt Child Health;deels uit WKZ Fonds en Catharijnestichting

Intervention

Keyword: cardiovascular, children, follow-up, PCOS

Outcome measures

Primary outcome

Primary study parameter/endpoint:

To determine cardiovascular health in offspring of PCOS mothers during childhood and to compare it with children from non-PCOS mothers. The main study parameters consist of cardiovascular measurements.

• Age of 2.5-4 years:

Physical examination: anthropometry, blood pressure

Cardiovascular parameters: pulse wave velocity, echocardiography (systolic and diastolic function of the right and left ventricle)

Sample: saliva sample

• Age of 5-8 years:

Physical examination: anthropometry, blood pressure

Cardiovascular parameters: intra-abdominal and subcutaneous fat, carotid intima media thickness (CIMT), vascular stiffness.

Samples: serum, saliva sample

Secondary outcome

To determine pulmonary health in offspring of PCOS mothers during childhood and to compare it with children from non-PCOS mothers:

• Age of 2.5-4 years:

Pulmonary parameters: Interrupter resistance (Rint®)

• Age of 5-8 years:

o Pulmonary parameters: interrupter resistance (Rint®), spirometry,

inflammatory markers (nitric oxide) in exhaled air

Study description

Background summary

Polycystic ovary syndrome (PCOS) is a complex and frequent disorder with a heterogeneous clinical presentation varying throughout life, from birth up to post-menopause. Although mostly known for its reproductive consequences, PCOS is associated with metabolic abnormalities related to insulin resistance and obesity. Children born from PCOS mothers are considered to be at risk for early insulin resistance, leading to development of PCOS and metabolic abnormalities in childhood and adolescence. Obesity and insulin resistance are considered as states of low- and pro-inflammation associated with endothelial dysfunction. In addition, it has been shown that endothelial dysfunction develops from the first decade of life in response to genetic and environmental risk factors. Therefore, offspring of women with PCOS may be at increased risk for vascular disease later in life. Moreover, some evidence suggests that early life respiratory disease also contributes to later life cardiovascular consequences. The number of studies on offspring of PCOS mothers is low and a systematic follow up of children born form PCOS mothers has not been performed yet. We propose a systematic evaluation of cardiometabolic and pulmonary health characteristics of children (aged 2,5-8 years) born from mothers diagnosed with PCOS. A saliva sample will be performed to determine the biochemical androgenic status of the children.
Mothers of these children have undergone standardized phenotyping prior to conception; we will therefore be able to correlate the metabolic status of the mother around the time of conception and the cardiometabolic and pulmonary health of their offspring.

Study objective

Primary objectives of the pilot study
• To determine childhood cardiovascular health in offspring of PCOS mothers and

to compare it with children from non-PCOS mothers.

Secondary objectives of the pilot study
• To compare cardiovascular risk factors between age groups
• To determine the childhood androgenic biochemical status in offspring of PCOS mothers and to compare it with children from non-PCOS mothers
• To determine childhood pulmonary health in offspring of PCOS mothers and to compare it with children from non-PCOS mothers
• To relate childhood cardiovascular health in offspring of PCOS mothers to their mothers around time of conception

Future objective of the main study
To form a cardiovascular prediction model for children of PCOS mothers in a longitudinal study.

Study design

Design: cross-sectional case-control study
Duration: 12 months
Setting: Single-centre study. Wilhelmina Children*s Hospital (WKZ) in Utrecht.

Study burden and risks

Since the pathogenesis of CVDs is known to start early in life and symptoms of cardiovascular disease become present later in life, early factors associated with the pathogenesis of CVDs have to be studied in children. Due to new techniques (Luminex®) in the laboratories of the department of pediatric immunology, it is now possible to study adipocytokines in small amounts of serum.
It is believed that at the age of 5-8 years, blood sampling is minimally invasive as the participants will probably understand the context and the aim of the research. We therefore think that this blood sample to obtain information on adipocytokines is justified in these children aged 5-8 years.
Subjects will have no benefit form participating to this study. The risks associated with participation in this study are very small and the possible complications are non-severe. Moreover, there is a risk of developing a haematoma after the venous puncture. These risks have a short duration and are non-severe.
The study related burden for the subjects will be minimized by using local anaesthetics before the puncture will be conducted and a small needle will be used. Moreover, the venous puncture will only be performed once. If the venous puncture fails, the child will not be punctured for a second time, unless the child and their parents give their permission.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Cases:
-Children of mothers with PCOS at the age of 2.5-4 years or 5-8 years;Controls:
-Children with the age of 2.5-4 years or 5-8 years
-Mothers of these children must have had a regular cycle and conceived naturally

Exclusion criteria

-Language barrier
-Children with a history of a heart defect
-Children with a respiratory infection or respiratory infection two weeks previous to the visit (they are asked to reschedule the appointment)
-Residency outside the Netherlands

-Children with Diabetes Mellitus type I
-Children with unresolved medical conditions

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):	31-12-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	13-08-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-06-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-08-2014

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-11-2014
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	NL40568.041.12