

Complications of PCOS Pregnancy: Evaluating Risk

Published: 01-04-2008

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To design a multivariate prediction model of pregnancy outcome in women with PCOS with the intention to define intervention strategies for the future.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine disorders of gonadal function
Study type	Observational invasive

Summary

ID

NL-OMON40046

Source

ToetsingOnline

Brief title

CoPPer

Condition

- Endocrine disorders of gonadal function
- Pregnancy, labour, delivery and postpartum conditions
- Gonadotrophin and sex hormone changes

Synonym

anovulation, PCOS

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: Maternal Complications, Neonatal Outcome, PCOS, Pregnancy

Outcome measures

Primary outcome

Maternal and perinatal complications in women with PCOS.

Secondary outcome

Several secondary outcomes will be studied as well. For example:

Miscarriage rate.

Maternal complications such as; Gestational diabetes, pregnancy induced hypertension, pre-eclampsia.

Perinatal complications such as; Pre-term birth, abnormal birth weight, admission to a neonatal ward.

Study description

Background summary

PCOS is a heterogeneous condition in which metabolic disturbances such as insulin resistance are common. Pregnancies in women with PCOS are reported to have an increased chance of being complicated by gestational diabetes, pregnancy induced hypertension and pre-eclampsia. Subsequently their offspring are reported to have a lower birth weight and higher risk of admission to a neonatal intensive care unit. However, the cause of increased complication rate is not yet identified.

There is evidence that intra-uterine conditions as well as pre- and periconception factors influence not only neonatal outcome, but also long-term health of the child. Therefore early detection and treatment of pregnancy complications is important for both mother and child.

In order to identify high risk PCOS pregnancies, the specific effects of PCOS on pregnancy in comparison to the background effects need further investigation. Preconceptional risk assessment of PCOS women is needed to improve antenatal

health care and pregnancy outcome of PCOS pregnancies in the future.

Study objective

To design a multivariate prediction model of pregnancy outcome in women with PCOS with the intention to define intervention strategies for the future.

Study design

Prospective multi-centre follow-up cohort study.

Study burden and risks

The burden associated with participating in the study will be mostly originating from repetitive blood sampling. Participation in the study may be of some benefit to the women since they will be monitored more closely than in normal antenatal care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Women diagnosed with PCOS (according to Rotterdam criteria) who wish to conceive
- Age 18-40yr

Exclusion criteria

Age <18 or >40yr, unresolved other medical conditions, Diabetes type 1

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	17-04-2008
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date: 01-04-2008

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 12-08-2008

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 05-11-2014

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	NL20244.041.07