Spiral Artery Remodelling (SPAR) in Normal Pregnancy and Pre-eclampsia * Pilot Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON39443

Source
ToetsingOnline

Brief title
SPAR study

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Vascular hypertensive disorders

Synonym
preeclampsia, toxemia of pregnancy

Research involving
Human

Sponsors and support

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

Southampton, Division of Human Development and Health

Intervention

Keyword: acute atherosis, cardiovascular disease, placental bed biopsy, preeclampsia

Outcome measures

Primary outcome

Primary endpoint is the evaluation of a systematic pathologic scoring system

for placental bed lesions

Secondary outcome

The secondary endpoint is a feasibility score for placental bed biopsies.

Thirdly, vascular pathology between both groups will be compared and scored.

Also the additional value of the analysis in Southampton to the scoringsystem

will be evaluated. The future endpoint of the main study encompasses the

correlation between pathological score of placental bed from pregnancies

complicated by pre-eclampsia or intrauterine growth restriction and

cardiovascular health of the mother. Therefore samples from the pilot study

will also be used for the intended main study.

Study description

Background summary

There is considerable concern about the link between a cluster of pregnancy complications initiated by vascular pathology of the placental bed spiral arteries (pre-eclampsia and intrauterine growth restriction) and cardiovascular risk of the mother. At present, little is known about the mechanisms underlying abnormal vascular development and remodelling of the myometrial spiral arteries during pregnancy. We hypothesize that shared metabolic, immunological and vascular pathways are responsible for abnormal placentation, as well as future

cardiovascular risk of women.

Study objective

Main objective of this pilot study is to investigate the placental bed histological phenotype and evaluate a scoring system for lesion characteristics of the placental bed spiral artery in pre-eclampsia and uncomplicated pregnancy. The secondary objectives of the pilot study will be to determine the accuracy and yield of the placental bed biopsy technique to detect characteristic vascular lesions of spiral arteries in normal and abnormal placentation. With the above an initial comparison will be made of vascular pathology of the spiral artery between women with preeclampsia and/or IUGR and normal pregnancy. A long term objective is to investigate the correlation between the pathological score of placental bed and subsequent cardiovascular health of the mother in the main study.

Study design

Observational study (case-control setting)

Study burden and risks

Additional burden for participants will be minimal, as to the collection of an additional blood sample will coincide with routine sampling at the time of caesarean section. Tissue collection from the placenta, cord blood and placental bed biopsy collection has previously been performed in numerous women and is considered without any relevant risks.

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 having preeclampsia in need of a caesarean section Women having a intra uterine growth restriction in need of a caesarean section Women having a normal pregnancy in need of a caesarean section

Exclusion criteria

In case of operative complications in terms of, for example, excessive blood loss the surgeon in charge may decide that there is no time to perform the placental biopsies

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):	13-05-2012
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	11-01-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-12-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-09-2013
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	NL38881.041.11

Study results

Date completed:	21-07-2016
Actual enrolment:	159