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

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Main objective of this pilot study is to compare vascular lesions of the placental bed spiral artery characteristics in pre-eclampsia to spiral artery samples after an uncomplicated pregnancy. Aim of the pilot study will also be to determine the...

Ethical review	Not approved
Status	Will not start
Health condition type	Maternal complications of pregnancy
Study type	Observational invasive

Summary

ID

NL-OMON35300

Source
ToetsingOnline

Brief title
SPAR study

Condition

- Maternal complications of pregnancy
- 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

Intervention

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

Outcome measures

Primary outcome

Vascular lesions will be scored according to a systematic pathologic classification system; additional metabolic and immunological profiling of plasma and placental samples will be performed to investigate the link between maternal cardiovascular risks factors and vascular lesions of the placental bed due to defective spiral artery remodelling. The latter will be obtained through the SMART collaborative

Secondary outcome

not applicable

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 compare vascular lesions of the placental bed spiral artery characteristics in pre-eclampsia to spiral artery samples after an uncomplicated pregnancy. Aim of the pilot study will also 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. The aim of the main study will be to determine the link between spiral artery vascular pathology and subsequent cardiovascular health of the mother. Therefore all samples in the pilot study will be used 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:	Will not start
Enrollment:	70
Type:	Actual

Ethics review

Not approved

Date:	24-08-2011
Application type:	First submission
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	NL37592.041.11