# SPiral Artery Remodelling (SPAR) in Normal and Complicated Pregnancy

Published: 13-06-2016
Last updated: 16-04-2024

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Pregnancy, labour, delivery and postpartum conditions |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON43217

**Source**
ToetsingOnline

**Brief title**
SPAR study

### Condition

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

**Synonym**
intrauterine growth restriction, Intrauterine growth retardation, 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, immune system, intra uterine growth restriction, placental bed biopsy, preeclampsia

## Outcome measures

### Primary outcome

Primary endpoint is the correlation between pathological score of placental bed from pregnancies complicated by pre-eclampsia or intrauterine growth restriction and cardiovascular health of the mother. Placental bed pathology will be correlated to placental patholgy. De results of the pilot study will also be included in the analysis.

### Secondary outcome

- Utilize and further investigate the feasibility of our newly devised scoring system for spiral artery pathology and the myometrium.

- Assessments of feasibility, tissue sampling quality and yield for the detection of acute atherosis lesions in the placental bed.

- Investigate local maternal-fetal immune interactions involved in spiral artery remodelling (flow cytometry, transciptomic, mRNA, chromatin analysis)

# 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

The primary endpoint will be descriptive histology on placental bed biopsies and placenta in healthy pregnant women or women with preeclampsia and/or IUGR in need of caesarean section. In particular, the study will aim to find the degree of remodelling in the spiral arteries underlying placental disease as a primary endpoint, as well as determine the prevalence of other components of the scoring system for placental pathology. Comparison of placental (bed) pathology and cardiovascular health determinants of the mother will be a primary interest in this study.

### Study design

Observational study (case-control setting)

### Study burden and risks

Additional burden for participants will be minimal. The collection of an additional blood sample will mostly coincide with routine sampling at the time of caesarean section. Tissue collection from the placenta, cord blood and placental bed biopsy collection will occur under normal caesarean anesthesia and has previously been performed in numerous women and is considered without any relevant risks. Also, the pilot study showed no additional risk of biopsies being taking during cesarean section.

## 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/intrauterine growth restriction in need of a caesarean section.
Women having a normal pregnancy in need of a caesarean section

## Exclusion criteria

Both/Cases: 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.
Congenital abnormalities in the foetus.

# Study design

## Design

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|---|---|
| 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

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 08-08-2016 |
| Enrollment: | 536 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 13-06-2016 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 30-11-2016 |
| 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 | NL57021.041.16 |