# Cardiac adaptation and recovery after preeclampsia

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Heart failures |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON53038

**Source**
ToetsingOnline

**Brief title**
Cardiac recovery after pregnancy

### Condition

- Heart failures
- Pregnancy, labour, delivery and postpartum conditions
- Renal disorders (excl nephropathies)

**Synonym**
preeclampsia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht
**Source(s) of monetary or material Support:** Ministerie van OC&W,Er loopt momenteel een subsidievoorstel bij de nederlandse hartstichting. Deze is goedgekeurd.

## Intervention

**Keyword:** Cardiovascular, miRNA, postpartum, Preeclampsia

## Outcome measures

### Primary outcome

The pattern of cardiac recovery (in terms of cardiac geometry, function and miRNA expression) after a preeclamptic pregnancy compared to a normotensive pregnancy.

The relation between acute placental atherosis with subclinical coronary atherosclerosis at 12 months pospartum

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### Secondary outcome

Lifestyle (questionnaire)

Blood Pressure

Metabolic syndrome (MetS)

Kidney function

Glycocalyx thickness (by means of the Glycocheck)

Coronary artery calcification (CAC)

Carotid Intima media thickness

Flow mediated dilation

# Study description

### Background summary

Pregnancy is considered a cardiovascular (CV) stress test, and complicated pregnancies are associated with an increased risk for cardiovascular disease (CVD) later in life. Consequently, a better understanding of cardiac adaptation to pregnancy and cardiac recovery in the postpartum period in healthy and complicated pregnancy, may lead to a better understanding of maternal CV health later in life. Moreover, it is known that often the pregnancy induced CV adaptation does not resolve completely after a short postpartum (PP) period and it is not clear whether these induced changes will resolve over a longer period of time (i.e. in the upcoming months/years after delivery). Understanding the cardiac adaptation during pregnancy and the reversal process in the postpartum period, as well as the factors that influence this these processes, may provide us not only insight in this mechanism, but may help us in identifying factors that may be target points for modification.

On the other hand, preecalampsia is in many cases accompanied by soft plaque formation in the placenta, being defined as decidual vasculupathy or acute atherosis. This process resembles the pathological foam cell formation process in atherosclerosis that precedes coronary artery disease. As former preeclamtic women have an up to 8 fold increased risk for coronary artery disease, studying the link between placental acute atherosis and subclinical systemic atherosclerosis my aid in early detection of those women at risk.

## Study objective

The main goal of this study is to explore the pattern of physiologic and pathophysiologic cardiac recovery after a preeclamptic pregnancy compared to a normotensive pregnancy, up till 18 months PP.

To study the link between placental acute atherosis and subclinical systemic atherosclerosis

## Study design

This study is a longitudinal cohort study. The first measurement will be performed upon admittance for induction of labour or caesarean section, which corresponds with 48-24 hours before delivery. Further measurements will be performed in clusters at PP intervals of: 24-48 hours, 3 weeks, 6 weeks, 3 months, 6 months, 12 months and 18 months.

If women find the frequent visits a large burden, they may choose to participate in a short track study, meaning participating in visit 1, visit 2 and at 12 month visit 3 in order to answer our second primary objective. To participate in the short track, they should at least be willing to enter the study at delivery by providing their placenta for research and later the measurement at 12 months postpartum. Therfore it is allowed for the short track to miss the first and second measurement.

## Study burden and risks

The first visit of this study will be performed while the participant is administered for the induction of labour or caesarean section, thus an extra visit is not necessary. This is also true for the first PP measurements. The next 6 visits will be after the participant is discharged from the hospital and extra visits are necessary, except for the 6 weeks PP visit, which is a routine visit. The frequent visits may cause some discomfort, especially since our participants are young mothers who still need to take care of their child. During the measurement, one of our co-workers will assist in taking care of the newborn so that the participant can bring her child with her.
Each of the visits will last approximately 2 hours in the MUMC+. The only invasive procedure is a venapunction where 75 ml blood will be extracted. The only unfavourable side effect can be a small hematoma (rare). Clinically, participants will be advised based on their risk profile following standard *cardiovasculair risicomanagement*.
Transthoracic echocardiography will be performed by qualified technicians at the cardiovascular department at the MUMC+. Experience shows that this investigation is not experienced as uncomfortable. All measurements will be performed or supervised by an experienced researcher. These investigations are already approved previously in other METC applications (CMO-nr: 2008/226; 2009/004; 10-2-066). The other measurements (questionnaires, blood pressure (BP), weight measurement, urine collection and glycocalyx measurement) do not cause any discomfort for the patient besides the time that it takes. On the other hand, potential health improvement and early detection of CV risk profiles and initiation of already existing effective prevention strategies that improve lifestyle are important benefits.

We will start with inviting women to participate in the whole study. If they refuse due to the burden of the frequent visits, we will ask them whether they would be interested in a shorter study period in which they will only be measured at diagnosis, before delivery and at 12 months postpartum. At 12 months, also a coronary CTA will be performed to assess soft plaque formation and calcium score to answer our second objective. Besides, flow mediated dilation (FMD) and carotid intima media thickness (IMT) will be assessed. If they chose to participate in the complete study, they will be asked whether they are interested in doing the additional measurement of the short track aside as well as this will only mean that at 12 months postpartum, a CTA, IMT and FM measurement will be performed.
The CT exams are generally painless, fast and easy. There may be some discomfort from having to remain still for several minutes and with placement of an IV. This will feel as a pin prick when the needle is inserted into the vein. A warm, flushed sensation during the injection of the contrast materials and a metallic taste in the mouth that lasts for at most a minute or two may be experience. Besides, a sensation for urge to urinate can be felt; however, this is actually a contrast effect and subsides quickly. A beta-blocker will be

given beforehand in order to lower the heart rate below 70 bpm so that the lowest radiation dose can be used.

# Contacts

**Public**
Medisch Universitair Ziekenhuis Maastricht

P Debeyeplein 25
Maastricht 6229 HX
NL
**Scientific**
Medisch Universitair Ziekenhuis Maastricht

P Debeyeplein 25
Maastricht 6229 HX
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Cases consist of women (18 years or older) with preeclampsia (PE) in the current pregnancy (PE is defined as hypertension (systolic blood pressure >= 140 mmHg and/or diastolic BP >= 90 mmHg) developed after 20 weeks of pregnancy with de novo proteinuria (>= 300 mg/ 24 hours)), Controls are women (18 years or older) with an uncomplicated pregnancy (i.e no foetal or maternal placental complications, such as pregnancy induced hypertension, preeclampsia or HELLP-syndrome, or small for gestational birth infancies)

## Exclusion criteria

Cases
* Women who do not want to be informed about the results of the tests, or women who do not
want their general practitioner and specialist(s) to be informed about
the test results
* Known allergy for iodinated contrast (only if they chose to participate in a track including
the CTA measurement)
* Known contraindication for the use of betablockers or nitroglycerine

Controls
* Women with diabetes Mellitus and gestational diabetes
* Women with (suspected) IUGR in the current pregnancy (estimated fetal weight p<10)
* Preterm delivery of the current pregnancy ( gestational age <37 weeks)
* Women who do not want to be informed about the results of the tests, or women who do not
want their general practitioner and specialist(s) to be informed about
the test results
* Known allergy for iodinated contrast (only if they chose to participate in a track including
the CTA measurement)
* Known contraindication for the use of betablockers or nitroglycerine

# Study design

## Design

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| Study type: | Observational non 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): | 16-11-2016 |
| Enrollment: | 1754 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 03-09-2015 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 19-09-2016 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 19-04-2017 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 07-03-2018 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 05-09-2018 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 11-03-2020 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

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| Approved WMO Date: | 12-07-2023 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 02-07-2024 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 | NL52556.068.15 |