

Study of the perception of reduced fetal movements

Submission date 23/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/12/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/04/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The perception of reduced fetal movements occurs in a large number of pregnancies. Fortunately, the majority of these babies are absolutely fine. Reduced fetal movements might be caused by an altered fetal position or maternal distraction due to other activities. However, in some cases, the baby moves less because of suboptimal placental functioning. In this study, we assess if measuring the placental function with an ultrasound scan might be useful (the Cerebroplacental ratio (CPR) is an obstetric ultrasound tool used as a predictor of adverse pregnancy outcomes). If the placenta does not work properly, a reduced amount of nutrients and oxygen stream towards the baby. In that case, it might be better to deliver the baby early, but we are not sure about this. We want to assess if it is better to deliver the baby early, or to wait, in women who experience perceived reduced fetal movements at term and who have an abnormal ultrasound measurement.

Who can participate?

Women with reported reduced fetal movements at term.

What does the study involve?

This depends on the hospital. In half of the participating hospitals, the cerebro placental ratio (CPR) result is visible and treatment will be based on this result. In the other half of the participating hospitals, the result of the CPR is not visible (concealed) and treatment is thus not based on the CPR result and the usual standard protocol will be followed.

What are the possible benefits and risks of participating?

Participation in a hospital with visible CPR results:

Abnormal CPR:

Possible advantages: pursuing the start of labour within 16 hours in case of reduced fetal movements and an abnormal CPR result, may improve the outcomes of the baby, but we are not sure about this. The baby's outcome may theoretically improve as it will no longer be exposed to reduced oxygen and nutrients due to a placenta that does not function well. It may prevent a hospital admission for breathing support of the baby for example, or prevent an instrumental vaginal delivery (vacuum) or emergency caesarean section.

Possible disadvantages: By pursuing the start of labour within 16 hours in case of an abnormal

CPR result you cannot give birth at home. You will be admitted to the hospital and labour will be induced. The duration of labour can be longer compared to a spontaneous onset of labour.

Normal CPR:

In case of a normal CPR result, participating in this study will not confer any personal advantages, known disadvantages or extra risks. The mother will receive the usual maternity care. Participation helps us to improve future care of babies from women with reported reduced fetal movements.

Participation in a hospital with concealed CPR results:

Study participation will not confer any personal advantages, known disadvantages or extra risks for the mother or her baby. She will receive the maternity care as usual. Participation helps us to improve future care of babies from women with reported reduced fetal movements.

Where is the study run from?

University Medical Center Groningen (Netherlands)

When is the study starting and how long is it expected to run for?

November 2019 to April 2025

Who is funding the study?

ZonMw (Netherlands Organisation for Health Research and Development)

Who is the main contact?

Dr Sanne Gordijn, s.j.gordijn@umcg.nl

Study website

<https://www.zorgevaluatienederland.nl/evaluations/cepra>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

281168

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

NL6876804219, IRAS 281168

Study information

Scientific Title

The CErebro Placental RAtio as indicator for delivery in perception of reduced fetal movements

Acronym

CEPRA

Study objectives

Does expedited delivery (start <16 hours) in pregnancies at term with reduced fetal movements and an abnormal CPR (Cerebro placental ratio, <1.1) improve neonatal outcome?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/12/2019, Medical Ethics Review Board of the University Medical Center Groningen (P.O. Box 30 001, 9700 RB, Groningen, the Netherlands; +31(0)50 361 42 04; metc@umcg.nl), ref: METC2019/488

Study design

International cluster randomized controlled clinical trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

<https://www.zorgevaluatienederland.nl/evaluations/cepra>

Health condition(s) or problem(s) studied

Pregnant women with perceived reduced fetal movements at term.

Interventions

Hospitals will be randomized into either the 'revealed CPR' arm or either the 'concealed CPR' arm. Hospitals are randomized using a computer-generated algorithm (in Castor), stratified by country and number of deliveries per year.

After recruitment and consent, an ultrasound scan for fetal biometry, amniotic fluid volume, uterine artery pulsatility index, and CPR is performed. The pulsatility indices of both the umbilical artery and middle cerebral artery will be reported aside from the calculated CPR.

Depending on the cluster, clinicians will be either blinded or unblinded to the CPR. Expedited delivery is pursued in women with an abnormal CPR – defined as CPR <1.1 - in the open arm. In this case, we aim to start delivery within 16h or an elective caesarean section will be advanced. Women in the concealed arm will not have their CPR results revealed and will receive routine clinical care.

Intervention Type

Mixed

Primary outcome measure

The primary outcome is a composite of severe neonatal outcomes collected from medical files after delivery consisting of:

1. Stillbirth
2. Neonatal mortality
3. Apgar score <7 at 5min
4. pH <7.10 (umbilical artery)
5. Emergency delivery for fetal distress (need for cooling, caesarean section or ventouse/forceps)
6. Severe neonatal morbidity (respiratory distress syndrome, hypoxic ischemic encephalopathy, sepsis, necrotizing enterocolitis and supplementary oxygen therapy (>4days))

Secondary outcome measures

1. Mild and other neonatal outcomes (including hypoglycaemia, hypothermia and admittance to the neonatal ward) will be collected from medical files after delivery.
2. Child development and behaviour will be assessed using the validated Ages and Stages Questionnaire (ASQ-3) and Child Behaviour Checklist (CBCL/1.5–5) at 24 months postpartum.
3. Maternal health-related quality of life will be measured using the validated European Quality of Life 5-Dimension 5-Level (EQ-5D-5L) questionnaire at baseline, six weeks postpartum, 12 months postpartum and 24 months postpartum.
4. Maternal fear of childbirth is assessed using the validated Wijma Delivery Expectancy Questionnaire (WDEQ-A) at baseline.
5. Maternal experience of childbirth is assessed using the validated Wijma Delivery Experience Questionnaire (WDEQ-B) and posttraumatic stress disorder checklist for DSM-5 (PCL-5) at six weeks postpartum.
4. Analysis of maternal serum markers (PlGF, sFlt-1, and PlGF/sFlt-1 ratio) in the context of normal and abnormal CPR and in relation to (adverse) outcomes and baseline characteristics will be performed in a post-hoc analysis. The single maternal blood sample will be taken at baseline.
5. Whenever possible placentas will be stored to determine the accuracy of routine placental immunohistochemistry in a post-hoc analysis.

6. A cost-effectiveness analysis of monitoring-intervention strategy will be performed. A short-term and long-term cost-effectiveness analysis from a societal perspective will be performed as well as a budget impact analysis.

Overall study start date

25/11/2019

Completion date

01/04/2025

Eligibility

Key inclusion criteria

1. Singleton pregnancy with reported reduced fetal movements
2. Gestational age from 37+0 up to and including 40+6 weeks
3. Cephalic presentation
4. Normal cardiotocograph

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

2160

Key exclusion criteria

1. Maternal age <18 years
2. Inability to give informed consent
3. Small for gestational age (SGA)
4. Major congenital malformations or chromosomal abnormalities (that can influence pregnancy outcomes chosen for this study)
5. Indication for delivery within 4 days

Date of first enrolment

01/07/2020

Date of final enrolment

01/02/2025

Locations

Countries of recruitment

Australia

England

Netherlands

United Kingdom

Study participating centre
University Medical Center of Groningen
Netherlands
9713 GZ

Study participating centre
Amsterdam UMC, location AMC
Netherlands
1105 AZ

Study participating centre
Amphia hospital
Netherlands
4818 CK

Study participating centre
Gelre ziekenhuizen Apeldoorn
Netherlands
7334 DZ

Study participating centre
Medisch Spectrum Twente
Netherlands
7512 KZ

Study participating centre
Ziekenhuisgroep Twente
Netherlands
7609 PP

Study participating centre

Jeroen Bosch Ziekenhuis
Netherlands
5223 GZ

Study participating centre
Martini ziekenhuis
Netherlands
9728 NT

Study participating centre
Ikazia ziekenhuis Rotterdam
Netherlands
3083 AN

Study participating centre
Medisch Centrum Leeuwarden
Netherlands
8934 AD

Study participating centre
Flevoziekenhuis
Netherlands
1315 RA

Study participating centre
Amsterdam UMC, location VUmc
Netherlands
1081 HV

Study participating centre
Diakonessenhuis Utrecht
Netherlands
3582 KE

Study participating centre

Albert Schweitzer ziekenhuis
Netherlands
3318 AT

Study participating centre
Zuyderland medisch centrum
Netherlands
6162 BG

Study participating centre
Maastricht UMC
Netherlands
6229 HX

Study participating centre
Leiden UMC
Netherlands
2333 ZA

Study participating centre
OLVG Oost and West
Netherlands
1061 AE

Study participating centre
Saint Marys Hospital
Manchester university NHS Trust
Manchester
United Kingdom
M13 9WL

Study participating centre
Mater Hospital Brisbane
Australia
QLD 4101

Sponsor information

Organisation

University Medical Center Groningen

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.umcg.nl>

ROR

<https://ror.org/03cv38k47>

Funder(s)**Funder type**

Government

Funder Name

ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal as soon as possible after completing the trial and data analyses.

Intention to publish date

01/06/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. s.j.gordijn@umcg.nl

Requests for re-use of data will be evaluated by the Principal Investigator, who will check whether the research question falls within the scope of the informed consent. Data will be made available by the data manager and/or the principle investigator. Third party use of data is governed in part by IP rules and agreements, that will become available after publication of the main results. After an approved access request, it depends on the research question whether the access will involve all data or a selection of the data. The raw data containing direct identifiable information will be kept strictly separate from the processed data and can only be accessed by the data manager and the PI.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/04/2021	28/09/2021	Yes	No