The CErebro Placental RAtio as indicator for delivery in perception of reduced fetal movements (CEPRA-study)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22934

Source
Nationaal Trial Register

Brief title
CEPRA study

Health condition

Reduced fetal movements

Sponsors and support

Primary sponsor: University Medical Center of Groningen
Source(s) of monetary or material Support: ZonMw (852002034)

Intervention

Outcome measures

Primary outcome

Composite perinatal outcome: stillbirth and neonatal mortality (< 28 days), NICU admittance longer than 12 hours, APGAR score < 7 at 5 min, pH < 7.10 umbilical artery, emergency delivery for fetal distress, severe neonatal morbidity (respiratory distress syndrome (RDS),

hypoxic ischemic encephalopathy (HIE), sepsis, necrotizing enterocolitis (NEC), supplementary oxygen therapy (> 7 days)

Secondary outcome

• Mild and other neonatal outcomes (hypoglycaemia, hypothermia, admittance to neonatal ward).
• Long-term child outcomes (general health, development and behaviour).
• Maternal outcomes (health related quality of life, anxiety pre- and postpartum, hypertensive disorders of pregnancy).
• Maternal serum markers (PlGF, sFLt-1, and PlGF/sFLt-1 ratio).
• Accuracy of standard placental immunohistochemistry.

Study description

Background summary

Maternal perception of reduced fetal movements (RFM) occurs in 6-15% of pregnancies. A perceived reduction of fetal movements can result from harmless causes, such as altered fetal position or maternal distraction due to other activities or stress. In some cases however, RFM is an important sign of placental insufficiency. The major challenge for RFM lies in its high incidence and the low absolute chance that the fetus is severely compromised. The fear of these vital consequences leads to substantial overtreatment of patients who experience RFM.
Functional parameters, such as Doppler ultrasound and serum biomarkers can help distinguish the compromised fetuses from healthy fetuses. Redistribution of the fetal circulation, signaled by a low Cerebro Placental Ratio (CPR) reflects redistribution of the fetal circulation and is a compensatory adaptation to nutrient and oxygen deprivation caused by placental insufficiency. An abnormal CPR may identify compromised fetuses, also within normal weight ranges.
With this study we aim to assess if prompt start of delivery (<16 hours) in term pregnancies complicated by reduced fetal movements and an abnormal CPR (<1.1) improves neonatal outcome (including perinatal mortality and long-term (neurodevelopmental) outcome) and maternal outcome. We aim to reduce the over treatment of healthy fetuses with RFM and the under treatment of the fetuses at risk and, to investigate if a normal CPR predicts favorable neonatal outcome.

Study objective

Use of CPR as indicator for delivery in reduced fetal movements reduces perinatal mortality and improves neonatal outcome and long-term outcome.

Study design

Primary outcome: perinatal/neonatal period
Secondary outcome: Longterm neonatal outcomes at 2 years of age.

Intervention

Expedited delivery is pursued in women with an abnormal CPR (<1.1) in the open study arm. In this case we aim to start delivery within 16 hours 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.

Contacts

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Eligibility criteria

Inclusion criteria

Singleton pregnancies in cephalic presentation and normal cardiotocograph presenting with RFM beyond 37 weeks gestation

Exclusion criteria

• Small for gestational age, defined as an abdominal circumference

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2020
Enrollment:	2160
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	25-02-2019
Application type:	First submission

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
NTR-new	NL7557
Other	METc UMCG : METc2019.488

Study results