Routine obstetric medications and maternal heart rate variability

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23599

Source
Nationaal Trial Register

Brief title
MAMA-hart

Health condition

hypertensive disorders of pregnancy (HDP), threatened preterm birth (TPB), preterm premature rupture of membranes (PPROM), vaginal blood loss

Sponsors and support

Primary sponsor: Philips Electronics Nederland B.V.
Source(s) of monetary or material Support: Philips Research

Intervention

Outcome measures

Primary outcome

Investigate the effect of routine obstetric medications on maternal PPG features in complicated pregnancies, with specific focus on heart rate variability.

Secondary outcome

Investigate PPG features of women who deliver preterm.
Investigate the PPG features throughout different stages of delivery (compared to CTG data)
Investigate differences in PPG features between normotensive and hypertensive subjects.
Investigate PPG features at 6 weeks postpartum.

Study description

Background summary

This is a longitudinal, observational study. Participants will be pregnant women admitted to the maternity wards who will receive routine obstetric medications. The outcomes will be long-term, continuous photoplethysmography (PPG) and corresponding accelerometer data. These data will be acquired with a wrist-worn PPG device, similar to a smart-watch. This device is a CE-marked non-medical device. From these PPG, data features can be derived, for example heart rate (variability). Henceforth these will be referred to as PPG features.

The study will have two phases. In phase 1, data will be gathered during the subject's stay in the maternity ward. An in-patient comparison of the PPG features will be done between the epoch before and after drug administration. Upon discharge, the subjects will be invited to participate in phase 2 of the study, which takes place at 6 weeks postpartum. In phase 2, they will wear the wrist-worn PPG device for a full day. Data from the patients' electronic medical records (gathered as part of standard care) will be used to minimize confounding effects in data analysis and interpret the results.

Participating in this study has no effect on the treatment plan or clinical care of the subjects.

Study objective

Antenatal corticosteroids (a routine obstetric medication) reduces variability in maternal heart rate.

Study design

Niet-WMO ruling received: December 2019. Start of study: January/February 2020. End of study: December 2020.

Contacts

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Eligibility criteria

Inclusion criteria

- Aged 18 years and above
- Gestational age 23 5/7 to 33 6/7 weeks upon admission
- Yet to receive second dose of antenatal corticosteroids
- Proficient in Dutch or English

Exclusion criteria

- History of cardiovascular disease, specifically severe arrhythmia and congenital heart disease
- Cushing’s disease
- Known allergies for hard plastic (like in sport watches) or elastic band material.
- Presence of wounds, injuries or infectious diseases on the skin where the wrist-wearable device will be placed.
- Tattoo on top of wrist (where sensor should be placed)
- No space to place the device (as judged by the health care practitioner placing the device)
- Dexamethasone is given as antenatal corticosteroid instead of Betamethasone

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-04-2020
Enrollment:	61
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	06-12-2019
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	NL8204
Other	METC Máxima MC : N19.112

Study results