Intrapartum monitoring: a prospective observational cohort

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25099

Source
Nationaal Trial Register

Brief title
Intrapartum monitoring: a prospective observational cohort

Health condition

Every patient who delivers at our clinic

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

The main goal of this prospective observational study is to collect data to record maternal and neonatal outcomes of fetal monitoring during labour by using the conventional CTG (DU or FSE and TOCO). The collected data will be control data for an implementation study for the NI-fECG, which will be performed later this year.

Maternal outcomes: episiotomy and its indication, spontaneous vaginal deliveries and operative deliveries (vacuum extractions or caesarean section) with indication (fetal distress and/or failure to progress).
Neonatal outcomes: FBS during delivery, birth weight, gender, Apgar score, admission to a neonatal ward, pH in umbilical artery and vein.

Secondary outcome

The rate of deliveries in which placement of FSE was used, and how often FBS was performed.
Complications during delivery and postpartum: shoulder dystocia, intrapartum maternal fever, eclampsia, postpartum hemorrhage, thrombosis, wound infection, endometritis, mastitis.

This study serves as an important step towards prospective observational collection of data concerning monitoring during delivery on a larger scale. In addition, big data will provide reliable results concerning outcomes of obstetrical care in different subgroups in secondary and tertiary obstetric clinics.

Study description

Background summary

Rationale: There are two possibilities for non-invasive fetal monitoring: the conventional cardiotocogram (CTG) using Doppler ultrasound (DU) for the fetal heart rate (FHR) and external tocography (TOCO) for uterine contractions or the non-invasive fetal electrocardiography (NI-fECG) using electrical waveforms of the fetal heart to register FHR and electrohysterography (EHG) for uterine contractions. Currently the conventional CTG is used for fetal monitoring during labour.
Objective: The aim of this study is to prospectively collect data to record maternal and neonatal outcomes of fetal monitoring during labour by using the conventional CTG.
Study design: This is a multi-center prospective observational cohort study.
Study population: Pregnant women with fetal monitoring during delivery, carrying at least one living fetus. These women will act as a control group for an implementation study for the NI-fECG, which will be performed later this year. After inclusion of the first 200 women, we continue to include women as part of a large prospective observational multicenter cohort on fetal monitoring during labor and obstetrical outcomes. This study serves as an important step towards prospective observational collection of data concerning monitoring during delivery on a larger scale. In addition, big data will provide reliable results concerning outcomes of obstetrical care in different subgroups in secondary and tertiary obstetric clinics.
Intervention (if applicable): Standard care. All women during delivery will receive transducers placed on the abdomen: one above the fetal heart to monitor FHR (DU) and the other at the fundus of the uterus (TOCO) to measure frequency of contractions. A FSE is placed when the membranes are ruptured and FHR monitoring is insufficient by using DU. To obtain

complementary fetal information during labor, FBS can be needed and performed.
Main study parameters/endpoints: The primary outcomes are maternal and neonatal outcomes. Maternal outcomes: the percentage of episiotomy and its indication, the percentage of episiotomy and its indication, spontaneous vaginal deliveries, the percentage and indications of operative deliveries (vacuum extractions or caesarean section). Neonatal outcomes: percentage of FBS during delivery, gender, birth weight (dysmaturity and macrosomia), admission to neonatal ward with reason, Apgar score (<7 after 5 minutes), pH in umbilical artery and vein, severe metabolic acidosis (pH < 7.00 and base deficit ≥ 12 mmol/L). Secondary outcomes are the percentage of FSE that was used and how often FBS was performed. Complications during delivery: shoulder dystocia, intrapartum maternal fever, eclampsia, postpartum hemorrhage, thrombosis, wound infection, endometritis, mastitis.

Study objective

These women will act as a control group for an implementation study for the non-invasive fetal ECG, which will be performed later this year.

Study design

Standard care until 6 weeks postpartum

Intervention

None, standard care

Contacts

Public
Maxima Medical Center Veldhoven
Daisy van der Woude

040-8888384
Scientific
Maxima Medical Center Veldhoven
Daisy van der Woude

040-8888384

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: pregnant women who are admitted to the labor ward because of (induction of) labor or postpartum women who delivered at the labor ward with fetal monitoring during delivery, carrying at least one living fetus. Patients are only included after oral and written informed consent.

Exclusion criteria

None, monitoring standard care

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:	Recruiting
Start date (anticipated):	01-04-2019
Enrollment:	3000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type: Not applicable

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	NL7948
Other	METC Maxima MC Veldhoven : METC L19.039 / N19.032

Study results