HASTA study - Healthy Aging starts with a healthy STArt;Remote electrophysiological cardiotocography (eCTG), evaluation of feasibility in (a selected group of) complicated pregnancies from 32 until 37 weeks gestational age in a Home@Hospital setting: a prospective cohort study

Published: 05-11-2024
Last updated: 22-12-2024

To evaluate the feasibility of remote eCTG monitoring in complicated pregnancies between 32-37 weeks in a Home@Hospital setting. Secondary objectives are to evaluate automated interpretation of remote eCTG monitoring and to assess perinatal and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON57084

Source
ToetsingOnline

Brief title
HASTA

Condition

- Maternal complications of pregnancy

Synonym
pre-eclampsia (PE), Pregnancy complications: fetal growth restriction (FGR), preterm prelabor rupture of membranes (PPROM)

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Máxima MC (MMC);Technische Universiteit Eindhoven (TU/e);University Fund Eindhoven (UFE),NEMO Healthcare B.V., located at De Run 4630, 5504 DB Veldhoven, the Netherlands

Intervention

Keyword: complicated preganancy, eCTG, feasibility, home monitoring

Outcome measures

Primary outcome

The percentage of successful eCTG measurements in a Home@Hospital setting. This

will be defined as the necessity to switch to conventional CTG based on the

amount of signal loss.

Secondary outcome

Automated interpretation of eCTG monitoring, maternal and perinatal outcomes,

patients- and healtcare givers satisfaction and costs.

Additional outcome: Feasibility of synchronized multimodal acquisitions of

maternal and fetal measurements.

Study description

Background summary

Patients with obstetric complications like pre-eclampsia (PE), fetal growth restriction (FGR) or preterm pre-labour rupture of membranes (PPROM) often need

hospitalisation for fetal and maternal monitoring. Remote home monitoring has the potential to decrease the psychological and family burden of a hospital admission and to increase patient satisfaction while reducing health care costs due to a reduction in antenatal admissions. Previous research shows no indications that fetal home monitoring of selected complicated pregnancies imposes additional risks compared to in-hospital monitoring. Due to the limitations of conventional remote CTG monitoring like signal loss, electrophysiological cardiotocography (eCTG) has been developed and it is certified from 21 weeks of pregnancy onward. Since signal quality of eCTG in the preterm period - due to signal loss - is still unclear, the feasibility needs to be assessed first. The HASTA study will evaluate the feasibility of remote eCTG monitoring using non-invasive fetal electrocardiography (NI-fECG), Nemo Remote® Monitoring (NRM) in a hospital setting, as if the patient is at home (i.e., Home@Hospital setting). Automated interpretation will also be evaluated to support the healthcare giver in the future.
Additionally, this study will evaluate the feasibility of synchronized multimodal acquisitions of maternal and fetal measurements in a small population, aiming to understand the (patho)physiological mechanisms underlying cardiovascular function in pregnancy in the future.

Study objective

To evaluate the feasibility of remote eCTG monitoring in complicated pregnancies between 32-37 weeks in a Home@Hospital setting. Secondary objectives are to evaluate automated interpretation of remote eCTG monitoring and to assess perinatal and maternal outcomes, patient- and healtcare professionals satisfaction and costs. Additional objective is to evaluate the feasibility of synchronized multimodal acquisitions of maternal and fetal measurements.

Study design

A single center interventional prospective cohort study.

Intervention

Remote eCTG monitoring (using Nemo Remote®), daily in a Home@Hospital setting for 30-90 minutes, or at least twice weekly at the out-patient clinic.
Monitoring duration depends on signal quality and interpretability of the eCTG tracing, and lasts at least 30 minutes, and will be ceased after 90 minutes if the eCTG signal quality and/or interpretability is then still insufficient.
In 24 patients ultrasound clips of 2 x 5 minutes of the uterine and umbilical artery Doppler will be collected simultaneously to the eCTG measurement.

Study burden and risks

Participation in this study is expected not to cause any risk for the patient or fetus. In case eCTG registration is insufficient, a switch to the conventional CTG can be made. The benefits of eCTG monitoring with Nemo Remote® include the fact that it is wireless, non-invasive and well positionable without the help of elastic belts. As a result, repetitive repositioning to reduce signal loss - as required when using conventional CTG frequently performed with the support of healthcare professionals (HCPs) - is not needed. This is beneficial for future implementation of home monitoring throughout pregnancy, thereby increasing the patient's autonomy. Conducting self-administered remote eCTG home monitoring in a hospital setting, enables the evaluation of the feasibility at home - most likely - without any risk to patient or fetus. Patients using Nemo Remote® have a very small - known and unrelated to remote monitoring - probability of developing skin irritation or a minor (local) allergic reaction to the skin electrodes from the abdominal patch. There is no need for treatment if skin irritation happens, as this will naturally resolve over the course of days once the patch is removed. Measurements of the umbilical- and uterine artery are widely applied in routine obstetric care and are known not to cause any harm to patient and/or fetus (2). At three moments participants will be asked to fill in digital questionnaires. All other interventions are standard care. No additional - study-related - hospital visits or fetal registrations are needed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Minimum age of 18 years old
• Pregnant patients with a gestational age between 32+0 and 36+6 weeks and days
• Singleton pregnancy
• Any indication for fetal monitoring at least twice per week (e.g.): PE, FGR, PPROM
• Absence of exclusion criteria > 24 hours after admission.
• Oral and written informed consent

Exclusion criteria

• An indication for intravenous medication
• Blood pressure >160/110mmHg
• Absent-/or reversed flow umbilical artery Doppler
• HELLP
• Obstetric intervention expected <48 hours
• Clinical diagnosis of sepsis with hypotension
• Insufficient knowledge of Dutch or English language
• Insufficient comprehension of instruction Nemo Remote® or patient information
• Fetal and/or maternal cardiac arrhythmias
• Contraindications to abdominal patch placement (dermatologic diseases of the abdomen precluding preparation of the abdomen with abrasive paper)
• Patients connected to an external or implanted electrical stimulator, such as Transcutaneous Electro Neuro Stimulation (TENS) and pacemaker (because of disturbance of the electrophysiological signal).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	eCTG - Nemo Remote (NRM) NI-fECG
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-11-2024
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL87858.015.24