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Prediction of Preterm delivery by the Electrohysterogram

Submission date	Recruitment status	[_] Prospectively registered
05/12/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/07/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/02/2015	Pregnancy and Childbirth	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The electrohysterogram (EHG) is a new way of measuring contractions of the uterus. In this study the EHG will be used to monitor patients with premature contractions. The aim is to investigate whether the EHG can predict when delivery will occur.

Who can participate?
You can participate if you are admitted the hospital for imminent premature delivery between 24 and 34 weeks of gestation.

What does the study involve?
Besides the usual tests, you will have an additional test: the electrohysterogram (EHG). This means a measurement using a patch that is connected to the skin of your abdomen. The result will only be used for research and not for your treatment.

What are the possible benefits and risks of participating?
The measurement is not dangerous for you or your baby and has no side effects.

Where is the study run from?
The study will be run from the Maxima Medical Center in Veldhoven but four other hospitals in the Netherlands will participate as well.

When is the study starting and how long is it expected to run for?
The study started in March 2012 and will end in June 2014.

Who is funding the study?
This research is paid for by the Maxima Medical Center Veldhoven.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10620

Study information

Scientific Title
Prediction of Preterm delivery by the Electrohysterogram: an observational cohort study

Acronym
PoPE

Study objectives
The electrohysterogram is better predictor of preterm delivery than current diagnostics.

On 30/01/2014 the overall trial end date was changed from 01/02/2013 to 01/06/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee, Maxima Medical Center Veldhoven, 06/12/2011

Study design
Observational multicenter cross-sectional cohort study

Primary study design
Observational

Secondary study design

Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Preterm delivery, threatening preterm labor

Interventions
Electrohysterogram: power spectral density peak frequency, conduction velocity

Current diagnostics: digital examination, cervical length, fetal fibronectin

All diagnostics will be performed at admission: a 4-channel electrohysterogram recording of 30 minutes using a fixed electrode configuration, a digital examination, transvaginal cervical length measurement and fetal fibronectin testing. Electrohysterogram information will be blinded to the attending physician, analysis will be done afterwards. The peak frequency of the power density spectrum (by Fourier Transform) will be identified. For conduction velocity the corresponding action potentials will be visually identified in the different channels. The velocity (vector) will be calculated from these intervals from which the speed (scalar) will be used as conduction velocity.

Two cohorts will formed based on delivery within or after 7 days after measurement.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Sensitivity, specificity, positive and negative predicting value for predicting preterm delivery within 7 days from measurement

Secondary outcome measures
Area Under the Curve of the Receiver Operating Characteristic (ROC) curve for predicting preterm delivery within 7 days from measurement

Overall study start date
01/02/2012

Completion date
01/06/2014

Eligibility

Key inclusion criteria
1. Patients admitted for threatened preterm labor
2. Gestational age between 23+5 and 34+0 weeks
3. Clinically evaluated symptoms of preterm labor: at least 6 contractions in 60 minutes based on the (cardio) tocogram and/or maternal perception

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100

Key exclusion criteria
Patients in active labor: cervical dilatation ≥3cm

Date of first enrolment
01/02/2012

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Tannhauserdreef 272
Utrecht
Netherlands
3561HR

Sponsor information

Organisation
Maxima Medical Center (Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02x6rcb77

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Maxima Medical Center (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/06/2014		Yes	No