

Prediction of Preterm delivery by the Electrohysterogram

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| Submission date 05/12/2011 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 31/07/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 24/02/2015 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

Mr Hinke Lau

Contact details

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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 be 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 ≥ 3 cm

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

de Run 4600
Veldhoven
Netherlands
5404 DB
040 888 8384
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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 |