Evaluation of a Novel Diagnostic Kit for the Detection of Placental Alpha-Microglobulin-1 in the Prediction of Preterm Birth in Women Presenting With Signs and Symptoms of Preterm Labor

Published: 13-05-2014
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To assess the efficacy of the novel kit for the detection of PAMG-1 in the cervico-vaginal secretions of pregnant women with clinically intact membranes presenting with signs and symptoms of PTL in predicting time-to-delivery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Observational invasive

Summary

ID

NL-OMON46986

Source
ToetsingOnline

Brief title
PartoSure TTD test (Time To Delivery)

Condition

- Maternal complications of pregnancy

Synonym
pre term labor (PTL), threatening early birth

Research involving
Human

Sponsors and support

Primary sponsor: HAGAMEDICAL B.V.
Source(s) of monetary or material Support: geen

Intervention

Keyword: Cervical dilatation, Cervical lenght, PAMG-1, PTL

Outcome measures

Primary outcome

SN, SP, PPV, and NPV for the novel kit for the detection of PAMG-1, cervical

length measurements by trans-vaginal ultrasound (<30 mm), cervical dilatation >

1 cm, and contraction frequency >= 8 per hour for the following

presentation-to-delivery time intervals:

a. <= 48 hours

b. <= 7 days

c. <= 14 days

Secondary outcome

2. Association between results of the above tests and the following outcomes:

a. Delivery <37 weeks gestation

b. Admission to NICU

c. Histological chorioamnionitis

d. Funisitis

e. Respiratory distress syndrome

f. Patent ductus arteriosus

g. Neonatal sepsis

h. Birthweight

i. Perinatal death

Study description

Background summary

Accordingly, a device that is more sensitive in its detection of PAMG-1 than the AmniSure® ROM Test presumably will be able to detect more patients at risk for imminent delivery than its predecessor in patients presenting to labor and delivery units with signs, symptoms or complaints suggestive of preterm labor (PTL) who have no clinical evidence of membrane rupture. If this is the case, this tool may be of significant value to the provider in deciding how to manage their patients suspected to be at risk for imminent delivery. Management options may include administration of tocolytics to prolong gestation, corticosteroids to improve respiratory development, administration of antibiotics to decrease the risk of infection (intra-partum and post-partum), prescription of bed rest, as well as increased observation and fetal monitoring

Study objective

To assess the efficacy of the novel kit for the detection of PAMG-1 in the cervico-vaginal secretions of pregnant women with clinically intact membranes presenting with signs and symptoms of PTL in predicting time-to-delivery.

Study design

This is a prospective observational trial that will enroll pregnant women between 200/7 and 366/7 weeks of gestation that present with signs and symptom of preterm labor with clinically intact membranes and cervical dilatation <3 cm to assess how the results of novel kit for the detection of PAMG-1 in this patient group correlates to their time-to-delivery (TTD) and other adverse neonatal and pregnancy outcomes.

Study burden and risks

There is no potential conflict of interest. None of the investigators stand to benefit financially in any way, either directly or indirectly, from this study.

There are no additional potential risks involved in this study. The study involves only one additional clinical evaluation. Preterm labor/imminent delivery will be clinically diagnosed in accordance with accepted practices. The results of the novel kit for the detection of PAMG-1 will not be applied toward clinical decision making in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

signs and symptoms or complaints suggestive of preterm labor (PTL)
gestational age between 20 and 37 weeks
< 3 cm cervical dilatation
consenting to be part of tghe trial

Exclusion criteria

Rupture of fetal membranes (ROM)
receiving tocolytic medication prior collection of cervicovaginal specimens
cervical dilatation > 3 cm

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-12-2014
Enrollment:	196
Type:	Actual

Ethics review

Approved WMO

Date:	13-05-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	23-06-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	24-04-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-06-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-01-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL46920.098.13

Study results

Date completed:	11-10-2019
Actual enrolment:	110

Summary results
Trial is onging in other countries