European Fibronectin Study

Published: 26-07-2012
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This study will assess the capacity of quantitave fetal fibronectin testing as compared to or in addition of cervical length measurements and vaginal digital exams to predict preterm delivey in women with symptoms of preterm labour.

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

Summary

ID

NL-OMON37632

Source
ToetsingOnline

Brief title
EuFiS

Condition

- Maternal complications of pregnancy

Synonym
Preterm Labor

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Hologic

Intervention

Keyword: Fibronectin, Labor, Pregnancy, Preterm

Outcome measures

Primary outcome

Delivery within 7 days.

Secondary outcome

Gestational age at delivery, birth weight, neonatal morbidity, neonatal

mortality.

Study description

Background summary

Fetal fibronectin is an accurate predictor for the occurrence of preterm birth among women with threatened preterm labour. At present, the risk assessment for imminent preterm delivery consists either of observation of the frequency of contractions, vaginal examinations, cervical length measurements, and/or qualitative fibronectin testing. Women who are thought to be at high risk are treated with tocolytics and corticosteroids. The use of a quantitative fibronectin test might be a cost-effective strategy to reduce unnecessary treatment.

Study objective

This study will assess the capacity of quantitave fetal fibronectin testing as compared to or in addition of cervical length measurements and vaginal digital exams to predict preterm delivey in women with symptoms of preterm labour.

Study design

European multicenter prospective cohort study

Study burden and risks

NA

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

- Gestational age between 24-34 weeks
- Primary complaints or symptoms indicating threatened preterm delivery
- Intact membranes

Exclusion criteria

- Triplets or more foetuses
- Contra-indication for tocolysis

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):	18-02-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	11-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL39368.018.12