Costs and effects of fibronectin as a triage in women with threatened preterm labour.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27054

Source
NTR

Brief title
APOSTEL I

Health condition

Premature labor, Fibronectin, Cervical length measurement, Nifedipine, Tocolysis

Vroeggeboorte, Fibronectine, Cervixlengte, Nifedipine, Tocolyse.

Sponsors and support

Primary sponsor: Amsterdam Medical Center
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Number of days to delivery truncated at 7 days.

Secondary outcome

1. Neonatal mortality;

2. Neonatal morbidity;

3. Maternal morbidity (side effects of tocolytics);

4. Costs;

5. Health related quality of life.

Study description

Background summary

This study evaluates whether testing for fibronectin is a cost-effective strategy that prevents unnecessary treatment in women with threatened preterm labor. We will investigate a prospective cohort of women who are referred to a perinatal centre for spontaneous threatened preterm labor between 24 and 34 weeks with intact membranes. All women in the cohort will be tested for fibronectin and cervical length. High risk women with cervical length below 10 mm will be treated with tocolytics. Low risk women with a cervical length above 30 mm will be managed according to local protocol (tocolysis on discretion of physician). Woman with a negative fibronectin test and a cervical length between 10 and 30 mm will be randomised between nifedipine (intervention) and placebo (control) for 48 hours. The primary outcome measure will be delivery within 7 days. Secondary outcome measures will be neonatal morbidity and mortality, complications of tocolytics as well as costs.

Study objective

Fibronectin testing as a triage for women with threatened preterm labor is a cost effective strategy.

Study design

Interim analysis after inclusion of 200 patients.

Intervention

All patients will be tested for fibronectin and cervical length. Patients with a negative fibronectin test and a cervix between 10-30 mm will be randomly allocated to nifedipine or

placebo for 2 days. Patients with a positive fibronectin test will be treated with tocolytics and followed in the cohort.

Contacts

Public
Jolande Vis
[default]
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Scientific
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The Netherlands

Eligibility criteria

Inclusion criteria

1. Gestational age between 24 and 34 weeks;

2. Symptoms of preterm labor;

3. Cervical length between 10-30 mm;

4. Intact membranes.

Exclusion criteria

1. Dilation > 3cm;

2. Vaginal bleeding;

3. Signs of fetal distress that could lead to pregnancy termination;

4. Maternal disease (i.e. severe preeclampsia, HELLP syndrome) that could lead to pregnancy termination;

5. Previous treatment for threatened preterm labor in the current pregnancy;

6. Contra indications for nifedipine.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	220
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-06-2009
Application type:	First submission

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
NTR-new	NL1747
NTR-old	NTR1857
Other	80-82310-98-09056 : ZonMW
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A