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

Gepubliceerd: 24-06-2009 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27054

Bron
NTR

Verkorte titel
APOSTEL I

Aandoening

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

Vroeggeboorte, Fibronectine, Cervixlengte, Nifedipine, Tocolyse.

Ondersteuning

Primaire sponsor: Amsterdam Medical Center
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of days to delivery truncated at 7 days.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Interim analysis after inclusion of 200 patients.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Jolande Vis
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Gestational age between 24 and 34 weeks;

2. Symptoms of preterm labor;

3. Cervical length between 10-30 mm;

4. Intact membranes.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2009
Aantal proefpersonen:	220
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-06-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1747
NTR-old	NTR1857
Ander register	80-82310-98-09056 : ZonMW
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A