Apostel VI - Will a cervical pessary prolong pregnancy in women after an episode of threatened preterm labor.

Gepubliceerd: 16-10-2013 Laatst bijgewerkt: 18-08-2022

Women who remained undelivered after an episode of threatened preterm are at increased risk for preterm labor, half of these women will eventually deliver prematurely. No treatment is currently available for these women. This study will investigate...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28719

Bron
NTR

Verkorte titel
APOSTEL VI

Aandoening

Pregnancy, Preterm birth, Threatened preterm labor, Pessary

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Meibergdreef 9
Postbus 22660 1100 DD Amsterdam
The Netherlands
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Preterm delivery <37 weeks of gestation.

Toelichting onderzoek

Achtergrond van het onderzoek

Preterm labor is still the major contributor of perinatal morbidity and mortality.
Threatened preterm labor affects 9% of all pregnancies. Cervical length measurement and fibronectin or ACTIM-partus test can detect women who are unlikely to deliver. Of the other group a small percentage will delivery during the first admission for threatened preterm labor. For the women who remained undelivered, the risk of preterm birth is increased up to 50%. No treatment is currently available. By supporting the cervix, a pessary could prevent preterm birth or reduce the severity of prematurity and thereby the associated neonatal outcome.

6 september 2016: Study halted on the advice of the DSMC based on the results of the interim analysis.

Doel van het onderzoek

Women who remained undelivered after an episode of threatened preterm are at increased risk for preterm labor, half of these women will eventually deliver prematurely. No treatment is currently available for these women. This study will investigate if a cervical pessary is a solution for these high risk women, by supporting the cervix and to prolong pregnancy.

Onderzoeksopzet

Duration of the study will be 33 months:
1. We will need a run-in period of three months for the study set up;

2. Twenty-four months for inclusion of the required number of cases;

3. 6 months for follow-up data collection and report of results.

Onderzoeksproduct en/of interventie

Eligible women will be randomly allocated to receive either a cervical pessary or no intervention.
The cervical pessary will be placed in situ when undelivered, 48 hours after an episode of

threatened preterm labor and will stay in situ up to 36 weeks gestation or until delivery, whatever comes first.

Contactpersonen

Publiek

Academic Medical Center Amsterdam, Meibergdreef 9
F.J.R. Hermans
Amsterdam 110DD
The Netherlands
+31 (0) 20 566 4256

Wetenschappelijk

Academic Medical Center Amsterdam, Meibergdreef 9
F.J.R. Hermans
Amsterdam 110DD
The Netherlands
+31 (0) 20 566 4256

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-singleton/twin pregnancy

-GA between 24+0 and 34+6 weeks
- Cervical length >15mm-<30mm and positive fibronectin
- undelivered after 48 hours

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-major fetal abnormalities
-signs of intra-uterine infection
-ruptured membranes
-cervical dilatation > 3cm

-Residual cervical length that makes it impossible to place a pessary
-randomisation >72 hours after becoming eligible

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	16-10-2013
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	16-10-2013
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	NL4044
NTR-old	NTR4210
CCMO	NL45479.018.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A