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

No registrations found.

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

Summary

ID

NL-OMON28719

Source
Nationaal Trial Register

Brief title
APOSTEL VI

Health condition

Pregnancy, Preterm birth, Threatened preterm labor, Pessary

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Meibergdreef 9
Postbus 22660 1100 DD Amsterdam
The Netherlands
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Preterm delivery <37 weeks of gestation.

Secondary outcome

Neonatal outcomes; composite of neonatal morbidity (e.g. RDS, BPD, IVH, NEC, PVL, sepsis) and death.
Delivery outcomes: e.g. GA at delivery, time to delivery and preterm birth rates <34 and <32 weeks.
Maternal outcomes: side-effects, complications of pessary

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

-singleton/twin pregnancy

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

Exclusion criteria

-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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	16-10-2013
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

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

Study results

Summary results
N/A