Removal versus Retention of Cerclage in Preterm Premature Rupture of Membranes.

Gepubliceerd: 19-09-2012 Laatst bijgewerkt: 19-03-2025

The objective of this study is to determine whether retention of cerclage after PPROM reduces chorioamnionitis, improves latency (without a significant increase in chorioamnionitis), and lessens neonatal morbidity.

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

Samenvatting

ID

NL-OMON27694

Bron
NTR

Verkorte titel
PPROMCerclage

Aandoening

Premature Preterm Rupture Of Membranes, removal versus retention of cerclage.

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: Academic Medical Center (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine whether retention of cerclage after PPROM improves in terms of:
1. Chorioamnionitis (temp > 38oC plus fetal tachycardia or uterine tenderness);
2. Latency (the interval from membrane rupture to the onset of labor in days) without a significant increase in chorioamnionitis (temp > 38oC plus fetal tachycardia or uterine tenderness);
3. Composite Neonatal Outcome:
A. Fetal or neonatal death;
B. Respiratory distress syndrome;
C. Documented sepsis within 72 hours of delivery;
D. Grade 3 or 4 intraventricular hemorrhage;
E. Stage 2 or 3 necrotizing enterocolitis.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

The question of whether to remove cerclage after preterm premature rupture of membranes (PPROM) is one of the unresolved controversies in obstetrics. It is unclear whether latency (the interval from membrane rupture to the onset of labor) is prolonged with retention of the suture. Furthermore, some studies suggest an increase in major infectious maternal morbidity and possibly neonatal morbidity.

Objective:

The objective of this study is to determine whether retention of cerclage after PPROM reduces chorioamnionitis, improves latency (without a significant increase in chorioamnionitis), and lessens neonatal morbidity.

Study design:

Randomized trial performed in all ten perinatal centers in The Netherlands.

Study population:

Women with PPROM and cerclage between 22+0/7 – 32+6/7 weeks gestational age.

Intervention:

Random allocation to retention of cerclage or immediate removal of cerclage.

Main study parameters/endpoints:

Latency, chorioamnionitis as defined by temp > 38°C plus fetal tachycardia or uterine tenderness, Composite Neonatal Outcome, NICU stay, birth weight, estimated gestational age at delivery, postpartum endometritis and maternal sepsis.

Doel van het onderzoek

The objective of this study is to determine whether retention of cerclage after PPROM reduces chorioamnionitis, improves latency (without a significant increase in chorioamnionitis), and lessens neonatal morbidity.

Onderzoeksopzet

In view of the relatively small sample size, the fact that both treatments are already applied and are both mentioned in the Dutch guidelines, an interim analysis is not planned.

Onderzoeksproduct en/of interventie

Random allocation to retention of cerclage or immediate removal of cerclage.

Contactpersonen

Publiek

Academic Medical Centre
Dept Obstetrics and Gynaecology
T.S. Lange, de
Amsterdam
The Netherlands

Wetenschappelijk

Academic Medical Centre
Dept Obstetrics and Gynaecology
T.S. Lange, de
Amsterdam

The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. A previously placed prophylactic cerclage defined as any cerclage done ≤ 23+6/7 weeks including those done for previous history of cervical incompetence, asymptomatic cervical shortening (regardless of effacement) and asymptomatic cervical dilation ≤ 3 cm;

2. Spontaneous rupture of membranes 22+0/7 ¨C 32+6/7 weeks;

3. Singleton or twin gestation;

4. Shirodkar or McDonald cerclage in place ≥ 1 week.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Active labor (>8 uterine contractions per hour);

2. Chorioamnionitis as defined by temp > 38oC plus fetal tachycardia or uterine tenderness;

3. Placenta previa or undiagnosed vaginal bleeding;

4. Nonreassuring fetal status by nonstress test (NST) or biophysical profile (BPP);

5. Presentation > 48 hours after rupture of membranes;

6. Abdominal cerclage;

7. Cerclage done for symptomatic cervical dilation (cervix dilated > 3 cm);

8. Post amniocentesis membrane rupture (rupture which occurs within one week of amniocentesis).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-10-2012
Aantal proefpersonen:	142
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-09-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38330
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3469

Register	ID
NTR-old	NTR3621
CCMO	NL36460.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38330

Resultaten

Samenvatting resultaten
N/A