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

No registrations found.

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

Summary

ID

NL-OMON27694

Source
NTR

Brief title
PPROMCerclage

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: Academic Medical Center (AMC)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To compare these treatments in terms of:

1. NICU stay;

2. Birth weight;

3. Estimated gestational age at delivery;

4. Postpartum endometritis;

5. Maternal sepsis.

Study description

Background summary

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.

Study 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

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-10-2012
Enrollment:	142
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-09-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38330

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3469
NTR-old	NTR3621
CCMO	NL36460.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38330

Study results

Summary results
N/A