PC-study

No registrations found.

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

Summary

ID

NL-OMON26958

Source
Nationaal Trial Register

Brief title
PC-study

Health condition

preterm birth
history of preterm birth
short cervical length

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Preterm birth < 32 weeks of gestation

Secondary outcome

Neonatal outcomes

Maternal outcomes

Study description

Background summary

Preterm birth (PTB) is in quantity and in severity the most important pregnancy complication in

obstetric care in the developed world. A cervical pessary and a cervical cerclage are both considered

as potential preventive treatments for spontaneous PTB in women at increase risk due to a history

of preterm birth or a short cervical length. This study evaluates the hypothesis that a cervical pessary

is non-inferior to a cervical cerclage in women who are scheduled for cerclage based on their risk

profile for spontaneous PTB.

The study is a nationwide open-label multicenter randomized clinical trial. Eligible women will be

randomized <24weeks in case of previous preterm delivery and short cervical

length to either a cervical pessary or cervical cerclage or before 16 weeks in case a primary cerclage

is required. Both cervical pessary and cervical cerclage will be removed at 36 weeks of GA or until

delivery, whatever comes first.

The primary outcome will be delivery before 32 weeks (<32 weeks). Secondary outcomes will

be preterm rate birth before 24, 28, 34 and 37 weeks, time from intervention to delivery, (early)

premature rupture of membranes, maternal infection, maternal side effects and composite bad

neonatal outcome including both morbidity and mortality rate of children as well as costs.

Study objective

NA

Study design

We will need a run-in period of 3 months for the study set up, and 36 months for inclusion. After inclusion of the last patient, 6 months (additional pregnancy) will be needed for data collection and report of results. The first report on the primary outcome is expected at 4 years after the start of the study.

Intervention

Pessary

Cerclage

Contacts

Public
AMC
B. Koullali
Amsterdam
The Netherlands
-
Scientific
AMC
B. Koullali
Amsterdam
The Netherlands
-

Eligibility criteria

Inclusion criteria

1) Singleton pregnancy
2) previous preterm birth < 34 weeks of gestation
AND
3)cervical length < 25mm or less on transvaginal ultrasound before 24 weeks of GA
OR

Indication for primary cerclage before 16 weeks in current pregnancy based on obstetric history, according to local protocol

Exclusion criteria

1) Maternal age less than 18 years
2) Inability to give informed consent
3) Placenta praevia
4) Vasa praevia
5) Premature Prelabour Rupture of the Membranes (PPROM)
6) Cervical dilatation iY3cm
7) Cervical length 2mm
8) Identified major congenital abnormalities.
9) Women with clinical signs of chorioamnionitis or signs of intra uterine infection

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2014
Enrollment:	440
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 29-01-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47528
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4204
NTR-old	NTR4415
CCMO	NL47362.018.13
OMON	NL-OMON47528

Study results

Summary results
none