PC-study

Gepubliceerd: 29-01-2014 Laatst bijgewerkt: 15-05-2024

NA

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

Samenvatting

ID

NL-OMON26958

Bron
Nationaal Trial Register

Verkorte titel
PC-study

Aandoening

preterm birth
history of preterm birth
short cervical length

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Preterm birth < 32 weeks of gestation

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

NA

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Pessary

Cerclage

Contactpersonen

Publiek

AMC
B. Koullali
Amsterdam
The Netherlands
-

Wetenschappelijk

AMC
B. Koullali
Amsterdam
The Netherlands
-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	440
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:	29-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47528
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
none