Quadruple P

Gepubliceerd: 29-01-2014 Laatst bijgewerkt: 19-03-2025

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

Samenvatting

ID

NL-OMON26394

Bron
Nationaal Trial Register

Verkorte titel
Quadruple P

Aandoening

Obstretic labor, premature
Pessaries
Progesteron
cervical length
Prevention

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Achmea Healthcare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Composite adverse neonatal outcome

Toelichting onderzoek

Achtergrond van het onderzoek

Preterm birth is in quantity and in severity the most important issue in obstetric care in the developed world. Progestagens and cervical pessaries are both considered as potential preventive treatments. We aim to compare the effectiveness of vaginal progesterone and cervical pessary in the prevention of preterm birth in women with singleton and twin pregnancies with a short cervix. This study is a nationwide open-label multicenter randomized clinical trial with an economic analysis alongside it. Women with a singleton or twin pregnancy undergoing foetal assessment, at 18-22 weeks for singleton pregnancy and 16-22 weeks for multiple pregnancies, will be offered cervical length measurement. Women with a short cervix (singleton pregnancy 35 mm or less (11.5th percentile), multiple pregnancy less than 38 mm (25th percentile), will be invited to participate in a randomized clinical trial. Intervention are either daily progesterone 200mg which will be self-administered vaginally from time of randomization or the silicone cervical pessary which will be placed between 18-22 weeks for singletons or between 16-22 weeks for multiples. Both interventions will be applied until 36 weeks gestation or until delivery, whatever comes first. Primary outcome will be composite adverse neonatal outcome including both morbidity and mortality rate of children in the two groups. Secondary outcomes will be time to delivery, preterm birth rate before 28, 32, 34 and 37 weeks, days of admission in neonatal intensive care unit, maternal morbidity, maternal admission days for preterm labour and cost.

Doel van het onderzoek

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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, 9 months (additional pregnancy + post-partum period) 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 vs. Progesterone

Contactpersonen

Publiek

-
M.D. van Zijl
[default]
The Netherlands
-

Wetenschappelijk

-
M.D. van Zijl
[default]
The Netherlands
-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Singleton pregnancy and cervical length at 18 to 22 weeks of 35 mm or less (≤35mm) OR

2. Multiple pregnancy and cervical length at 16 to 22 weeks of less than 38 mm (<38mm)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cervical cerclage in this pregnancy
2. Maternal age less than 18 years
3. Identified major congenital abnormalities
4. Death of one or both of the foetuses
5. Previous spontaneous preterm birth before 34 weeks
6. Participation Quadruple P study in previous pregnancy
7. Cervical length < 2 mm
8. Cervical dilation >3cm

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	1020
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: 50366
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4203
NTR-old	NTR4414
CCMO	NL42926.018.13
OMON	NL-OMON50366

Resultaten

Samenvatting resultaten
None