

Preventing Preterm birth with Progesterone: Costs and effects of screening healthy women with a singleton pregnancy for a short cervical length.

Gepubliceerd: 26-10-2009 Laatste bijgewerkt: 13-12-2022

Progesterone treatment for women with a short cervical length is effective in reducing the risk of preterm delivery.

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

Samenvatting

ID

NL-OMON20454

Bron

Nationaal Trial Register

Verkorte titel

Triple P

Aandoening

preterm birth, short cervical length, progesterone, vroeggeboorte, cervixlengte, progesteron.

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: ZON-MW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is composite bad neonatal condition (death or severe morbidity). This composite morbidity rate contains the following variables:

1. Severe Respiratory Distress Syndrome (RDS);

 2. Bronchopulmonary Dysplasia (BPD);

 3. Intraventricular Haemorrhage grade II B or worse;

 4. Necrotizing Enterocolitis (NEC);

 5. Proven sepsis and death before discharge from the nursery.

- They will be measured until 10 weeks after the expected term date.

Toelichting onderzoek

Achtergrond van het onderzoek

Preventing Preterm birth with Progesterone: Costs and effects of screening healthy women with a singleton pregnancy for a short cervical length. To evaluate whether progesterone treatment for women with a short cervical length is effective in reducing the risk of preterm delivery. In addition to assess whether it is cost-effective to do so.

Doel van het onderzoek

Progesterone treatment for women with a short cervical length is effective in reducing the risk of preterm delivery.

Onderzoeksopzet

Initially we aim at 1920 women. To obtain this amount of women, we hypothesize that we have to screen 40.000 women. An independent DSMC will look at the data after inclusion of 10.000, 20.000 and 30.000 women for safety, effectiveness and futility. If available, the DSMC can take into account the results of trials running abroad. We will continue the study until January 1st 2014 or until recruitment is completed, whatever comes first.

Onderzoeksproduct en/of interventie

200 mg progesterone daily for 10-12 weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Capacitated women;
2. 18 years or older;
3. Singleton healthy pregnancy;
4. Two times a cervical length shorter than 25 mm: a cervical length shorter than 25 mm at 16-20 weeks gestation and a confirmation of this result with a repeat measurement of the cervical length at 20-22 weeks gestation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Women with a pregnancy with major foetal abnormalities, painful regular uterine contractions, a history of ruptured membranes or a cervical cerclage will be excluded. In

addition, women with a previous preterm birth are excluded as well.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2009
Aantal proefpersonen:	1920
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	26-10-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1961
NTR-old	NTR2078
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A