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

No registrations found.

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

Summary

ID

NL-OMON20454

Source
Nationaal Trial Register

Brief title
Triple P

Health condition

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

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: ZON-MW

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcomes are:

1. Delivery < 34 weeks;

2. Time to delivery;

3. Preterm birth rate before 32 and 37 weeks;

4. Days of admission in neonatal intensive care unit;

5. Maternal morbidity;

6. Maternal admission days for preterm labour;

7. Costs.

Moreover, we will look at growth, physical condition including close examination of the genital tract, and neurodevelopmental outcome of the offspring at 24 months (corrected) age.

Study description

Background summary

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.

Study objective

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

Study design

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 untill january 1st 2014 or untill recruitment is completed, whatever comes first.

Intervention

200 mg progestesteron daily for 10-12 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2009
Enrollment:	1920
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-10-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results
N/A