Screening healthy women with a singleton pregnancy for a short cervical length

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To evaluate whether a screening program with cervical length measurement to find women at risk for a preterm delivery, is cost-effective. Women with a short cervical length are asked to take part in a follow-up study (the Tripple P treat study) that...

Ethical review	Approved WMO
Status	Pending
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON33673

Source
ToetsingOnline

Brief title
Triple P screening study

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
short cervical length, threatened preterm birth

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cervical length, preterm birth, screening

Outcome measures

Primary outcome

Cervical length.

Secondary outcome

Secondary objective is evaluating the cost-effectiveness of screening for

cervical length.

Study description

Background summary

Spontaneous preterm delivery is the single most important cause of perinatal mortality in the Western world. Although it is already known that cervical length measurement at 20 to 22 weeks can identify women at increased risk for preterm delivery, an effective treatment has not been available until recently. In addition, there are no guidelines regarding cut-off values for cervical length available. In august 2007, Fonseca et al. published in the New England Journal of Medicine that the risk of preterm delivery in women with a shortened cervix could be decreased with 50% due to treatment with progesterone. However, there was no statistically significant effect on neonatal outcome, possibly due to a lack of statistical power.

Study objective

To evaluate whether a screening program with cervical length measurement to find women at risk for a preterm delivery, is cost-effective. Women with a short cervical length are asked to take part in a follow-up study (the Tripple P treat study) that evaluates whether subsequent progesterone treatment is effective.

Study design

Multicenter observational cohort study.

Study burden and risks

We don*t expect patients to experience the cervical length measurements as a burden. Patients exhibiting a short cervical length, have an increased risk of preterm birth. They will be asked to enter the follow-up clinical trial where progesterone is administered, which may possibly decrease the preterm birth rate.

Contacts

Public
Academisch Medisch Centrum

Postbus 22700
1105 DE Amsterdam
NL
Scientific
Academisch Medisch Centrum

Postbus 22700
1105 DE Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- capacitated women
- at least 18 years old

- healthy singleton pregnancy

Exclusion criteria

- major foetal abnormalities
- painful regular uterine contractions
- a history of ruptured membranes
- cervical cerclage
- a previous preterm birth

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2009
Enrollment:	38400
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL26332.018.08