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

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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.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Pregnancy, labour, delivery and postpartum conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON35507

**Source**
ToetsingOnline

**Brief title**
Triple P treat 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, progesterone

## Outcome measures

### Primary outcome

Bad neonatal outcome.

### Secondary outcome

-- delivery before 34 weeks

-- child health, growth and development at 2 years time to delivery

-- preterm birth rate before 32 weeks, and before 37 weeks

-- days of neonatal admission

-- maternal morbidity

-- maternal admission for preterm labour

-- costs

# 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 was until recently not 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 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 design

Multicenter randomised clinical trial.

### Intervention

Vaginal progesterone each night or placebo from 24 to 34 weeks of gestation.

### Study burden and risks

A minimal burden for the pregnant woman: from 24 to 34 weeks of gestation daily 1 vaginal capsule.
However, the pregnant woman could benefit a lot from participating in the trial: if progesterone indeed reduces the preterm birth probability, she does not have to undergo all problems related to preterm birth.

## Contacts

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## 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
- both measurements of cervical length were < 30 mm (Triple P screening study)

## Exclusion criteria

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

# Study design

## Design

| | |
|---|---|
| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

## Recruitment

NL
Recruitment status: Pending

| | |
|---|---|
| Start date (anticipated): | 01-02-2009 |
| Enrollment: | 1920 |
| Type: | Anticipated |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Generic name: | Progesterone |
| Registration: | Yes - NL outside intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 22-10-2009 |
| 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 |
|---|---|
| EudraCT | EUCTR2008-005987-15-NL |
| CCMO | NL25467.018.08 |