

# Pessary or Cerclage to prevent preterm delivery in women with short cervical length with and a history of preterm birth.

Published: 20-02-2014

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To evaluate whether cervical pessary can replace cervical cerclage in women with previous preterm birth and a short cervix or in women with a history of multiple preterm births in terms of effectiveness and costs

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Neonatal and perinatal conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON47528

### Source

ToetsingOnline

### Brief title

PC Study

### Condition

- Neonatal and perinatal conditions

### Synonym

preterm birth, preterm delivery

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** ZonMw

## **Intervention**

**Keyword:** cerclage, pessary, preterm birth, prevention

## **Outcome measures**

### **Primary outcome**

- delivery before 32 weeks.

### **Secondary outcome**

- delivery before 24 weeks
- delivery before 28 weeks
- delivery before 34 weeks
- delivery before 37 weeks
- time from intervention to delivery
- (early) premature rupture of membranes
- maternal infection
- maternal side effects, i.e. vaginal discharge, bleeding, discomfort, dyspareunia
- neonatal mortality; i.e. in-hospital death
- neonatal morbidity

## **Study description**

### **Background summary**

Preterm birth is a major problem within obstetrics and accounts for the majority of perinatal morbidity and mortality. When a women had a preterm delivery the risk of recurrence is increased. According to national guidelines women with a history of preterm birth are closely monitored with regular visits

to the outpatient clinic and are treated with progesteron. During these 2-weekly prenatal visits the cervical length is measured. In case a cervical length of 25 millimetres or less is measured, women receive a cerclage. In women with a history of multiple preterm births a cerclage is offered early in pregnancy (before 16 weeks) irrespectable of cervical length.

Placing a cerclage is an invasive surgical procedure requiring hospital admission.

Recent studies have demonstrated that a pessary, a silicone band folded around the cervix, is effective in reducing preterm birth in women who have a short cervical length. This is a non-invasive procedure which takes place at the outpatient clinic and takes about 10 minutes. This is a patient-friendly intervention and a much cheaper alternative compared to cerclage. Therefore it is necessary to asses it's effectiveness in this group of patients.

Hypothesis: we estimate that a pessary is as effective as a cerclage against lower costs.

## **Study objective**

To evaluate whether cervical pessary can replace cervical cerclage in women with previous preterm birth and a short cervix or in women with a history of multiple preterm births in terms of effectiveness and costs

## **Study design**

Nationwide multicentre RCT with an economic analysis alongside it.

## **Intervention**

Pessary versus cerclage inserted for 23+6 weeks of pregnancy

## **Study burden and risks**

In context of this research the burden for patients will be minimal. When compared to the control group, who receive standard care, burden of the intervention group is even less, because this group doesn't has to undergo an invasive procedure.

# **Contacts**

## **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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

### Inclusion criteria

1. Singleton pregnancy
  2. History of preterm birth before 34 weeks of gestation
- AND
3. Cervical length of 25mm or less on transvaginal ultrasound before 24 weeks of GA
- OR
- Indication for primary cerclage before 16 weeks in current pregnancy based on obstetric history, according to local protocol

### Exclusion criteria

- placenta previa
- vasa previa
- age less than 18 years
- inability to give informed consent
- identified major congenital abnormalities
- Premature Prelabour Rupture of the Membranes (PPROM)
- Cervical dilatation 3cm or more

-Signs of infection or fetal distress

## Study design

### Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	26-03-2014
Enrollment:	350
Type:	Actual

### Medical products/devices used

Generic name:	Pessary
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	20-02-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	16-04-2014
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	25-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	28-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	13-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	08-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	15-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	18-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	19-08-2014
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	26-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	02-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	09-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	24-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	31-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	01-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	09-06-2015
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	01-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	14-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	24-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	29-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	05-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	16-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	21-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	24-04-2017
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	23-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	01-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	27-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	31-07-2020
Application type:	Amendment
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

ID: 26958

Source: Nationaal Trial Register

Title:

### In other registers

Register	ID
CCMO	NL47362.018.13
OMON	NL-OMON26958