

# Prostaglandins or balloon for induction of labour at term

Published: 14-01-2009

Last updated: 05-05-2024

To assess in term pregnant women with an unfavourable cervix (Bishop score < 6, Appendix1) the effectiveness of induction of labour with a transcervical Foley catheter as compared to induction with prostaglandins.

<b>Ethical review</b>	-
<b>Status</b>	Pending
<b>Health condition type</b>	Pregnancy, labour, delivery and postpartum conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32572

### Source

ToetsingOnline

### Brief title

PROBAAT

### Condition

- Pregnancy, labour, delivery and postpartum conditions

### Synonym

induction of labour

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** foley catheter, induction of labour, prostaglandin, term

## Outcome measures

### Primary outcome

Caesarean section rate

### Secondary outcome

Safety and Cost of both methods

## Study description

### Background summary

Induction of labour is an intervention designed to artificially initiate uterine contractions leading to progressive dilatation and effacement of the cervix and birth of the baby. Induction of labour is a common procedure: twenty-two percent of all deliveries were induced in the Netherlands in 2007. Compared to the spontaneous onset of labour, induction of labour is associated with prolonged labour, more instrumental deliveries and a higher rate of caesarean sections, especially when the cervix is unfavourable. A recent Dutch survey showed a wide variety of methods being in use for induction of labour, intravaginal prostaglandin gel being used most frequently. A less frequently utilized method of ripening the uterine cervix is the transcervical Foley catheter. This inexpensive method is reported to have similar success-rates to induction of labour with intravaginal prostaglandins, and is associated with fewer abnormalities of contraction pattern and a lower caesarean section rate.

### Study objective

To assess in term pregnant women with an unfavourable cervix (Bishop score < 6, Appendix1) the effectiveness of induction of labour with a transcervical Foley catheter as compared to induction with prostaglandins.

### Study design

Multicentre Randomized Controlled Clinical Trial

## Intervention

Induction of labour with a transcervical Foley catheter as opposed to intravaginal prostaglandins

## Study burden and risks

Because we will compare two standard procedures, there will be no extra risk or burden for participants of the study.

## Contacts

### Public

Academisch Medisch Centrum

Meibergdreef 9  
1105 AZ Amsterdam  
NL

### Scientific

Academisch Medisch Centrum

Meibergdreef 9  
1105 AZ Amsterdam  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- \* Term pregnancy (\*37 weeks of pregnancy)
- \* Scheduled for induction of labour
- \* Vital singleton pregnancy
- \* Intact membranes
- \* Unfavourable cervix (Bishop score < 6)
- \* Cephalic presentation

## Exclusion criteria

- \* Previous caesarean section
- \* Placenta praevia
- \* Hypersensitivity for one of the products used for induction

## Study design

### Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	812
Type:	Anticipated

### Medical products/devices used

Generic name:	foley catheter
Registration:	Yes - CE outside intended use
Product type:	Medicine
Brand name:	Cytotec
Generic name:	Misoprostol

Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Propess
Generic name:	Dinoproston
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Prostin gel
Generic name:	Dinoproston
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Prostin tablet
Generic name:	Dinoproston
Registration:	Yes - NL intended use

## Ethics review

Not available

## 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	EUCTR2008-006246-26-NL
CCMO	NL25271.018.08