# ‘Foley catheter for induction of labour filled with 30mL or 60mL’

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27767

**Source**
Nationaal Trial Register

**Brief title**
FILL study

**Health condition**

- Inleiding van de baring
- Foley katheter

- Induction of labour
- Foley catheter

### Sponsors and support

**Primary sponsor:** W.J. van Wijngaarden
Bronovolaan 5, 2597 AX Den Haag
tel: 070 312 4141
e-mail: WvWijngaarden@bronovo.nl
**Source(s) of monetary or material Support:** Initiator is sponsor

### Intervention

### Outcome measures

### Primary outcome

The main study parameter is delivery versus no delivery within 8 hours after the membranes are artificially ruptured.

### Secondary outcome

• Induction (placement of the Foley catheter) to delivery time

• Number of deliveries within 24 hours after Foley catheter placement

• Induction (placement of the Foley catheter) to catheter expulsion time

• Amniotomy to delivery time

• Bishop score after catheter expulsion

• Duration of use and dose of oxytocin between amniotomy and delivery

• Mode of delivery

• Umbilical cord prolapse

• Maternal and neonatal morbidity

## Study description

### Background summary

To assess, in term pregnant women with an unfavourable cervix, the time interval between the start of induction of labour and delivery using a Foley's catheter filled with 30mL of fluid compared with a Foley's catheter filled with 60mL of fluid.

### Study objective

In term pregnant women with an unfavourable cervix (Bishop score < 6, Appendix1) the time interval between induction of labour and birth with a transcervical Foley catheter filled with 60mL is significant quicker and equally safe than with a transcervical Foley catheter filled with 60mL.

### Study design

Vaginal swab culture (taken at Foley's catheter insertion)

Questionnaires after delivery

**Intervention**

Intervention: Foley catheter filled with 60mL

Control: Foley catheter filled with 30mL

## Contacts

**Public**

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## Eligibility criteria

### 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

• Maternal age <18years

• Severe congenital malformations

• Prior caesarean section

• Placenta praevia

• Hypersensitivity for one of the products used for induction

• Latex allergy

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-02-2014 |
| Enrollment: | 0 |
| Type: | Actual |

# Ethics review

Positive opinion
Date: 09-12-2015
Application type: First submission

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 39008
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL5345 |
| NTR-old | NTR5578 |
| CCMO | NL44078.098.13 |
| OMON | NL-OMON39008 |

# Study results

**Summary results**
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