‘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
NTR

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

Bronovolaan 5

W.J. van Wijngaarden
Den Haag 2597 AX
The Netherlands
tel: 070 312 4141
Scientific

Bronovolaan 5

W.J. van Wijngaarden
Den Haag 2597 AX
The Netherlands
tel: 070 312 4141

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
--