Foley catheter for Induction of Labour filled with 30ml or 60ml

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Primary objective: To assess 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 30mL compared to induction of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON39008

Source
ToetsingOnline

Brief title
The FILL study

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Induction of labour

Research involving
Human

Sponsors and support

Primary sponsor: Bronovo Ziekenhuis
Source(s) of monetary or material Support: Bronovo Research Fonds

Intervention

Keyword: Foley catheter, Induction, Priming, Volume

Outcome measures

Primary outcome

The main study parameter will be the time interval between start of induction and delivery.

Secondary outcome

Costs of induction

- Resource use will be derived from the Case Report Form.

- Different methods and sources will be used to estimate unit costs as valuations for documented volumes of resource use. For maternal and neonatal admissions, delivery and neonatal monitoring, unit costs will be estimated with data from the financial department of Bronovo hospital. For use of the labour room and the operating theatre, unit costs are calculated per hour, using a bottom-up approach. For some cost units, national standardised prices will be used, and for laboratory testing, published tariffs will be used. Medication prices will be derived from the Pharmacotherapeutic Compass.

Induction to delivery time (deliveries within 12 hours, and 24 hours, of Foley catheter placement)

Induction to catheter expulsion time

Bishop score after catheter expulsion

Mode of delivery

Umbilical cord prolapse

Maternal morbidity

- Hyperstimulation (defined as more than six contractions in ten minutes over a minimal period of two times ten minutes, or a contraction lasting more than three minutes)

- Uterine rupture

- Placental abruption

- Maternal infection

- Fever (defined as an aural temperature * 38°C) during labour or within one week post partum

- Foetal tachycardia

- Start of intravenous antibiotics

- Endometritis within one week post partum

- Vaginal swab culture

Post partum haemorrhage (defined as an estimated blood loss of >1000 cc)

Neonatal morbidity

- Apgar scores <7 after 1 and 5 minutes

- Umbilical cord pH < 7.10

- Admissions to the neonatal ward due to suspected infection

- Proven infection

- Other admissions to the neonatal ward

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, if not the most common, obstetrical procedure: twenty-two percent of all deliveries in the Netherlands in 2007 were induced. 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 in use for induction of labour, with intravaginal prostaglandin gel used most frequent. [Reijers 2009] A less frequently used method of cervical ripening is the transcervical Foley catheter. Another recent Dutch randomised controlled trial reported a similar success-rate of induction of labour when compared with intravaginal prostaglandins with fewer maternal and neonatal side-effects. In that study, the Foley catheter was filled with 30mL of sterile saline. [Jozwiak 2011]

Embrey and Mollison first used a Foley catheter filled with 50mL for cervical ripening in 1967. [Embrey 1967] Since then, various volumes of insufflation were reported. Most studies used 30mL of saline to fill the balloon because it was thought that more volume would only increase the balloon diameter minimally and thus would not promote additional cervical dilatation. However, others thought that insufflating the balloon up to 80mL would increase cervical dilatation and more endogenous prostaglandin secretion.

When directly comparing different insufflation volumes, several studies have reported similar succes rates when the balloon catheter is filled with either 60mL or 80mL compared with 30mL with more deliveries within 24 hours of Foley catheter placement [Levy 2004, Kashanian 2009] and within 12 hours of placement [Delaney 2010] with the larger insufflation volumes. When oxytocin was started after expulsion of the catheter, Levy et al found that the larger inflation size was significantly associated with a higher rate of postripening dilatation of 3cm or more (76% compared with 52%) and, in primiparous, it resulted in a higher rate of deliveries within 24 hours (71% compared with 49%) as well as a decreased need for oxytocin augmentation (69% compared with 905). When comparing a 80mL with a 30mL Foley catheter, the number of favorable Bishop scores, change in Bishop score and overall vaginal delivery rate were all significantly better in the 80mL group as compared with the 30mL group.[Kashanian 2009]

Approximately 50% of the women in both groups in the study by Delaney et al. had received some form prostaglandin prior to Foley catheter placement and intravenous oxytocin infusion was started within 30 minutes of Foley catheter placement. Levy et al. removed the Foley catheter 12 hours after placement, after which oxytocin augmentation was started, (regardless of dilatation) and only performed artificial rupture of membranes when the woman had at least 3 painful contractions per hour and when cervical dilatation exceeded 3cm. In the study by Kashanian et al., the Foley catheter was removed 6 hours after placement, after which oxytocin augmentation was started, regardless of

dilatation. Also, a 500mL weight was attached to the end of the catheter.

The methodological aspects of these studies do not reflect the Dutch national guideline for induction of labour which recommends cervical priming in case of an unfavourable cervix, followed by artificial rupture of membranes once the cervix has been judged to be favourable. Augmentin of labour using oxytocin may be started in case of insufficient contractions. [NVOG Richtlijn Inductie 2006] Traction on the catheter has reported not to be of influence on the succes rate of induction of labour and may be unnecessarily painful and may inhibit free ambulation during this stage of labour.

A shorter time from induction to delivery due to a larger Foley catheter balloon inflation may lead to a decrease in the duration of labour, maternal exhaustion and hospitalization costs, without increased caesarean delivery rates and maintaining both neonatal and maternal safety.

Study objective

Primary objective: To assess 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 30mL compared to induction of labour with a transcervical Foley catheter filled with 60mL.

Secondary objectives: To study maternal and neonatal morbidity, to study the costs of both methods.

Study design

Non-blinded Open-label Randomised Controlled Clinical Trial will be held in a hospital setting starting in the spring of 2013 lasting until all necessary inclusions are met.

Intervention

Transcervical Foley catheter filled with 30mL or a transcervical Foley catheter filled with 60mL.

Study burden and risks

In this study the same method of induction (Foley catheter) with a different volume will be compared. No experimental medication will be used. No additional physical examination is needed for this study, nor will extra blood be taken from the subjects. One vaginal swab will be taken at moment of catheter insertion. No additional risks or burden are expected from the study. A questionnaire will have to be filled in after insertion of the catheter, asking

about painscores, physical discomfort and urination problems.

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

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 fetal congenital malformations
Prior caesarean section
Placenta praevia
Hypersensitivity for one of the products used for induction

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2014
Enrollment:	174
Type:	Actual

Medical products/devices used

Generic name:	transcervical balloncatheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	26-11-2013
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 27767
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL44078.098.13
OMON	NL-OMON27767