Induction of labour in hospital with a Foley catheter or oral misoprostol versus induction of labour at home with a Foley catheter or oral misoprostol

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Is priming of the cervix, as part of induction of labour:* At home cost-effective and safe compared to the hospital?* with oral misoprostol cost-effective and safe compared to a Foley catheter?

Ethical review	Not approved
Status	Will not start
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON48395

Source
ToetsingOnline

Brief title
PROBAAT-III

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Induction of labour

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Subsidie van ZonMW

Intervention

Keyword: Foley catheter, Induction of labour, Misoprostol

Outcome measures

Primary outcome

The main endpoint regarding safety will be a composite outcome of neonatal asphyxia (defined as a neonatal pH*7.05 and/or 5 minute Apgar<7), mortality (intrapartum/neonatal/perinatal) or NICU admission.

The main endpoint for effectiveness will be the percentage of vaginal deliveries.

Secondary outcome

Number of Foley catheters used/ misoprostol gifts

Induction to delivery time

Spontaneous or artificially ruptured membranes

More than one induction agent required

Mode of delivery

Use of analgesics during labour

Use of oxytocin (for induction or augmentation)

Use of tocolytics

Postpartum hemorrhage, need for a blood transfusion

Uterine hyperstimulation

Maternal death

Cardiorespiratory arrest

Hysterectomy for any complications resulting from birth

Intensive care admission

Pulmonary embolus or stroke

Maternal birth trauma (2nd, 3rd or 4th degree tears)

Maternal satisfaction/ preferences about both induction and labour

Total admission time, ante and postpartum.

Total amount of re-admissions before scheduled admission in home group and

reasons for readmission

Maternal infection

Meconium stained liquor

Gender

Birth weight

Apgar scores

Admissions to the neonatal ward/NICU and reason why

Extensive cost analysis (see protocol paragraph 8.1.2)

Study description

Background summary

Induction of labour is an obstetric intervention that artificially initiates labour. It is applied around 37000 times (22, 6% of all deliveries) each year in the Netherlands, which makes it the most frequently applied obstetric procedure. Approximately 50% of the women whose labour is induced have an unfavourable cervix at the start of induction. In these women, cervical ripening is required. Cervical ripening can be achieved with mechanical methods, such as a Foley catheter, or pharmacologically with prostaglandins. Regardless which method is used, cervical ripening takes time, and women stay admitted at the labour ward. This challenges the cost-effectiveness of this procedure. Outpatient cervical ripening could be a solution. The use of an

outpatient Foley catheter could potentially save almost 1000 euro per woman, which could give a substantial reduction in costs. Until now there is not sufficient evidence to know which method is preferred by women nor which is the safest and effective to use in outpatient settings, neither the cost-effectiveness.

The aim of this trial is twofold, we will compare safety, (cost)effectivity and patient preferences of misoprostol compared to a Foley catheter and of clinical (inhospital) versus outpatient (at home) cervical priming.

Study objective

Is priming of the cervix, as part of induction of labour:
* At home cost-effective and safe compared to the hospital?
* with oral misoprostol cost-effective and safe compared to a Foley catheter?

Study design

A nationwide multicentre open label 2 by 2 factorial randomized controlled trial with a cost-effectiveness and patientpreference analysis.

Intervention

1. Misoprostol at home
2. Foley catheter at home.

Study burden and risks

Both misoprostol and a Foley catheter are standard care in hospitals in the Netherlands and outside the Netherlands as methods to ripen the cervix as part of induction of labour. Misoprostol is not yet registered in the Netherlands as an agent for induction of labour. However, it is registered by Azanta Denmark A/S for this indication in several countries in the European Union (e.g. France, Denmark, Norway and Sweden) under the brand name Angusta®. A recent Cochrane review recommends a dosage of 20 to 25 mcg orally(2).

The Foley catheter is registered as a medical device to provide drainage of the urinary bladder, therefore in this study it will be studied outside the intended use. However, it is advised in national and international guidelines (3, 4) to use as for induction of labour and studied extensively. The firm Cook® Medical has developed a similar product, the Cook® Cervical Ripening Balloon which is registered for cervical ripening.
A recent systematic review and meta-analysis compared the Foley catheter to the Cook® catheter. It concluded both devices to be equally effective and safe but stated the Foley catheter to remain the logical choice over the Cook® catheter since the Foley is significantly cheaper, more widely available and accessible

and has a longer history of use (5).

The PROBAAT-II trial proved both misoprostol and the Foley catheter to be safe methods for both mother and child(6). It might be beneficial for women to await the results of priming at home rather than being admitted to the hospital: increased patient satisfaction but also possibly with a better effect on the priming itself. Non-inferiority of the treatment effects is expected with regard to safety for mother and child, but we do expect benefit of costs and increased patient satisfaction.

An analysis of women*s experience and preferences of participating women in the PROBAAT-II*trial showed women in the Foley group prefer more often to choose a different method for future inductions compared to women in the oral misoprostol group (6% vs 12%, RR 0.70, 95% CI 0.55-0.90). There was no other significant difference in experience between the two methods(6, 7).

After labour we will ask patients to fill out a questionnaire (ca. 30 minutes) about their experience of the method and location of priming and their labour. Our trial beholds no additional checks or examinations neither for mother nor for the newborn.

The WHO advises an oral dose of 25 mcg every 2 hours. The Dutch guideline is currently under revision. It advises an oral dose of 25 mcg every 2 hour or 50 every 4 hour. When oral admission is not possible or when time to labour is an important factor it advises a vaginal admission (25-50 mcg every 4 hours).

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

Vital singleton pregnancy in cephalic presentation
Intact membranes
Gestational age of 37 weeks or more
Unfavourable cervix (Bishop score <6)
Indication for induction of labour

Exclusion criteria

History of a Caesarean section or other uterine surgery with risk of uterine rupture
Non-reassuring cardiotocography
Suspected severe fetal growth restriction defined as EFW Doppler's
Placenta praevia or vasa praevia
Women with an indication for clinical observation (such as pre-eclampsia)
Non-engaged fetal head
Allergy for misoprostol
Aged younger than 18 year
Fetal lethal or major congenital anomaly
Fetal chromosomal abnormality (e.g. trisomy 21)
Severe kidney failure defined as an eGFR <15 ml/min/1.73m2
Liver failure
Inability to reach hospital within 30 minutes by own transport
Insufficient ability to communicate in Dutch or English by phone
Not willing or able to provide written informed consent

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:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	2828
Type:	Anticipated

Medical products/devices used

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

Ethics review

Not approved

Date:	03-10-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2018-003981-15-NL
CCMO	NL67815.041.19