Induction of Labour with a Foley catheter or Misoprostol at Term

Published: 21-05-2012
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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 misoprostol.

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

Summary

ID

NL-OMON39523

Source
ToetsingOnline

Brief title
PROBAAT-II

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, misoprostol

Outcome measures

Primary outcome

The primary outcome will be a composite of complications of uterine hyperstimulation, i.e. asphyxia and fluxus post partum. We will also compare the instrumental delivery rate.

Secondary outcome

Mode of delivery (Caesarean section, vaginal instrumental delivery) and the reason for instrumental delivery, i.e. suspected fetal distress and arrest of labour.

Costs

Induction to delivery time

Maternal morbidity

Hyperstimulation (defined as more than five contractions in ten minutes over a minimal period of two times ten minutes with and without FHR changes)

Hypertone uterus (defined as a contraction lasting more than three minutes)

Uterine rupture

Maternal infection

- Fever (defined as a rectal temperature >= 38°C) during labour or within one week post partum

- Foetal tachycardia

- Start of intravenous broad-spectrum antibiotics

- Endomyometritis within one week post partum

Neonatal morbidity

Meconium -stained liquor

Epidural analgesia

Apgar scores <= 7 at 1 and 5 minutes

Umbilical cord pH < 7.10

Womans satisfaction (deze misschien eruit laten voor nu?)

Oxytocine use

Admissions to the neonatal ward

Study description

Background summary

Rationale: 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. 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. We recently showed that the use of a Foley catheter resulted in an equal vaginal delivery rate as Prostaglandine E2 for a lower rate of hyperstimulation, resulting in less asphyxia and less hemorrhage. Another prostaglandine that is frequently used for induction of labour is misoprostol. As direct comparisons between misoprostol and Foley catheter are lacking, we propose a randomized comparison on the subject.

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 misoprostol.

Study design

Multicentre Randomized Controlled Clinical Trial

Intervention

Induction of labour with a transcervical Foley catheter as opposed to oral misoprostol

Study burden and risks

In this study two well established methods of induction of labour will be compared, that both are mentioned in the Guidelines of the Dutch Society for Obstetrics and Gynaecology. No additional physical examination is needed for this study, nor will extra blood be taken from the subjects. A possible additional burden might be the use of a vaginal speculum for placement of the transcervical Foley catheter. Patient satisfaction will also be one of the study outcomes.

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

Previous caesarean section
Placenta praevia
Hypersensitivity for one of the products used for induction
Maternal age <18 years
Lethal congenital anomaie

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:	Recruitment stopped
Start date (anticipated):	18-07-2012
Enrollment:	1760
Type:	Actual

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

Ethics review

Approved WMO Date:	21-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	23-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2011-000026-30-NL
CCMO	NL35278.018.11

Study results

Date completed: 01-11-2013

Actual enrolment: 1869

Summary results
Trial is onging in other countries