A pilot randomized controlled trial of delayed versus immediate oxytocin infusion after amniotomy for induction of labour.

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

Summary

ID

NL-OMON45440

Source
ToetsingOnline

Brief title
DEAL-pilot study

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
augmentation of labour, Induction

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis

Source(s) of monetary or material Support: NVT Scriptie onderzoek;ongefinancierd

Intervention

Keyword: Amniotomy, Induction, Labour, Oxytocin

Outcome measures

Primary outcome

Amniotomy to delivery interval.

Patient satisfaction.

Secondary outcome

Process of delivery:

- Amniotomy-to-oxytocin interval

- Meconium stained fluid

- Use of pain relief

- Intrapartum fever

- CTG FIGO-classification

- Micro-blood-examination

- Uterine hyperstimulation

Outcome of delivery:

- Total oxytocin augmentation time

- Total oxytocin dose

- Highest oxytocin dose

- Mode of delivery

- Haemorrhagia post partum

- Apgarscore <7 at 5 minutes

- Neonatal infection

Pilot evaluation

- The enrolment rate

- Rate and reason of violation of study protocol

Study description

Background summary

Common practice in induction of labour is to perform an amniotomy and start with oxytocin infusion. Avoidance of oxytocin infusion in induction of labour may result in higher patient satisfaction and prevention of side effects. Especially in women with low or medium risk induction indications (such as prolonged pregnancy (>41wks of pregnancy), mild hypertensive disorders, diabetes or maternal request) the increase of labour duration is thought be acceptable and advantages may be reached.

Study objective

The objective of this pilot study is to get a preliminary understanding of the amniotomy-to-delivery interval, patient experience and risks by awaiting spontaneous contractions after amniotomy. Simultaneously we*ll be able to evaluate the process of randomizing the induction-method.

Study design

Pilot randomized controlled trial.

Intervention

Awaiting spontaneous contractions for 12 hours after amniotomy, compared to standard care (immediate oxytocin infusion after amniotomy).

Study burden and risks

Labour may be prolonged due to awaiting spontaneous contractions, especially for nulliparous women. Prolonged rupture of membranes (>18 hours) is a risk factor for early onset group B streptococcal sepsis. There is a potential

increased risk of maternal infections. No increased risk of neonatal adverse events is expected.

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

- Due for induction of labour for the following maternal or fetal indications:
o prolonged pregnancy (>41wks of pregnancy)
o mild hypertensive disorders
o diabetes
o expected macrosomia
o maternal request.
- Term pregnancy (37-42 weeks of pregnancy)
- Singleton pregnancy

- Cephalic presentation of the fetus
- Viable fetus
- Favourable cervix (bishop score >5) and intact membranes
- >= 18 years old
- Sufficient command of the Dutch or English language

Exclusion criteria

- Previous caesarean section
- Fetal distress prior to induction
- Maternal fever prior to induction
- Contra-indication for oxytocin

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):	05-11-2017
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2017

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-01-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL60566.100.17