Continued versus discontinued oxytocin stimulation of labour in a double-blind randomised controlled trial

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To investigate whether discontinuation of Syntocinon® infusion after the onset of active labour decreases caesarean section rates compared to usual care; continuation of oxytocin until the baby and placenta is born.

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

Summary

ID

NL-OMON47801

Source
ToetsingOnline

Brief title
Disco

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
artificially stimulating childbirth, Induction of labour

Research involving
Human

Sponsors and support

Primary sponsor: Randers Regional Hospital, Department of Obstetrics and Gynecology
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hyperstimulation, Induction, Labor, Oxytocin

Outcome measures

Primary outcome

Delivery by caesarean section

Secondary outcome

- Birth experience and satisfaction 4 weeks postpartum (Childbirth Experience Questionnaire, CEQ1, Dencker 2010)

- Maternal: Instrumental vaginal delivery, duration of the active phase of labour (from time of randomisation to delivery), total duration of labour (from initiation time of oxytocin stimulation until delivery), duration of admission on the delivery ward, hyperstimulation, use of epidural analgesia, dose and duration of oxytocin infusion, episiotomy, rupture of the anal sphincter, uterine rupture, volume of blood loss at delivery and postpartum, need for evacuation of retained products of conception, use of antibiotics during labour, re-admission, retention of urine requiring catheterisation.

- Neonatal: Birth weight, CardioTocoGram (CTG) classification13, fetal scalp pH values, Apgar score at 1 and 5 minutes, umbilical cord arterial and venous pH and blood gas values, use of antibiotics, hyperbilirubinaemia, neonatal admission, need for resuscitation (bag and mask or intubation, time to onset of spontaneous ventilation), or death.

- Breastfeeding (time to established feeding and duration of exclusive breastfeeding)

Study description

Background summary

In The Netherlands 22% of all deliveries in 2013 were induced with synthetic oxytocin (Syntocinon®). Although Syntocinon® is used in a high proportion of labours, many professionals are unaware that oxytocin belongs to the top 10 of most dangerous medications used in a hospital (ISMP List of High Alert Medications) and underestimate the adverse effects. The most frequent complication is tachysystole, which increases the risk of fetal distress and birth asphyxia, requiring delivery by caesarean section or forceps/ventouse. Our hypothesis is that when the Syntocinon® infusion is stopped after the onset of active labour the caesarean section rates will decrease compared to usual care. Furthermore we expect better neonatal outcomes, less need for painrelief and more satisfaction of the mother.

Study objective

To investigate whether discontinuation of Syntocinon® infusion after the onset of active labour decreases caesarean section rates compared to usual care; continuation of oxytocin until the baby and placenta is born.

Study design

International multicentre, double-blind randomised controlled trial

Intervention

Discontinuation of the Syntocinon® infusion once active labour has been established.

Study burden and risks

It is possible that the delivery will take some more time for the women in the intervention group. We expect benefit for the intervention group as discontinuation of the Syntocinon® infusion will reduce the risk of hyperstimulation and the consequences involved.

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

Women with a singleton pregnancy with a gestational age of more than 37 weeks, a fetus in the
cephalic position, induced with intravenous oxytocin in the active phase of labour are eligible for the trial

Exclusion criteria

1. <18 years
2. Unable to read and understand the patient information or/and unable to give informed consent.
3. Non-cephalic presentation
4. Multiple gestation
5. Abnormal fetal heart rate pattern (cardiotocogram, CTG) before Syntocinon® initiation
6. Fetal weight estimation > 4500 g (clinical or ultrasonic)
7. Gestational age less than 37 completed weeks

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-03-2018
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Syntocinon®
Generic name:	Oxytocin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	24-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-12-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	20-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2019
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	EUCTR2015-002942-30-NL
ClinicalTrials.gov	NCT02553226
CCMO	NL57146.018.16