Intra uterine pressure monitoring for augmentation or induction of labour with intravenous oxytocin: Benefits and costs.

Gepubliceerd: 09-09-2005 Laatst bijgewerkt: 18-08-2022

Our hypothesis is that use of an IUPC, during augmentation or induction of labour with intravenous oxytocin, will reduce the number of instrumental deliveries from 25% to 16%.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25086

Bron
NTR

Verkorte titel
The IUPC study

Aandoening

Monitoring frequency and strenght of uterine contractions by IUPC (intervention) or external monitoring (control) during induction or augmentation of labour with intravenous oxytocin.

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: local funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of instrumental deliveries, i.e. caesarean sections and/or assisted vaginal delivery.

Toelichting onderzoek

Achtergrond van het onderzoek

In The Netherlands, approximately 10.000 deliveries are induced with oxytocin and 15.000 deliveries are augmented each year (LVR 2, 2002).
Many clinicians monitor frequency and strength of contractions with an intrauterine pressure catheter (IUPC). It is questionable whether monitoring contractions with IUPC is beneficial in terms of maternal or fetal outcome and whether it is cost effective.

- The aim of the study is to evaluate the effectiveness of IUPC in comparison to external monitoring during induction of labour.

Women will be at random allocated to placement of an IUPC (intervention group) or external uterine activity monitoring (control group).

- The primary outcome measure will be the number of instrumental deliveries, i.e. caesarean sections and/or assisted vaginal delivery.
- Secondary outcome measures are the occurrence of neonatal admittance to ICU, need for antibiotics by mother or child, total amount of oxytocin used, complications, time to delivery and costs.

- The study will be designed as an equivalence study. Under the assumption of equal neonatal and maternal morbidity, it is hypothesised that IUPC will reduce the number of instrumental deliveries from 25% to 16%. Analysis will be by intention to treat.

Doel van het onderzoek

Our hypothesis is that use of an IUPC, during augmentation or induction of labour with intravenous oxytocin, will reduce the number of instrumental deliveries from 25% to 16%.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Intra uterien pressure monitoring with a catheter during labour.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women with the indication to induce labour or to stimulate the contractions with intravenous oxytocin in case of arrest of labour.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Women with a history of caesarean section;

2. Gestational age<36 weeks;

3. Intra uterine fetal death;

4. Breech presentation;

5. Multiple pregnancy;

6. Maternal age<18 years;

7. HIV- or hepatitis B-infection;

8. Inta uterien infection;

9. Contra indication for amniotomy;

10. Participation in another RCT.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2004
Aantal proefpersonen:	1350
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005

Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL247
NTR-old	NTR285
Ander register	: N/A
ISRCTN	ISRCTN13667534

Resultaten

Samenvatting resultaten
N/A