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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25086

**Source**
NTR

**Brief title**
The IUPC study

**Health condition**

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

### Sponsors and support

**Primary sponsor:** none
**Source(s) of monetary or material Support:** local funding

### Intervention

### Outcome measures

**Primary outcome**

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

### Secondary outcome

1. The occurrence of neonatal admittance to NICU;

2. Need for antibiotics by mother or child;

3. Total amount of oxytocin used;

4. Complications;

5. Time to delivery and costs.

## Study description

### Background summary

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.

### Study objective

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%.

**Study design**

N/A

**Intervention**

Intra uterien pressure monitoring with a catheter during labour.

# Contacts

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# Eligibility criteria

## Inclusion criteria

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

### Exclusion criteria

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.

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-07-2004 |
| Enrollment: | 1350 |
| Type: | Actual |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 09-09-2005 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL247 |
| NTR-old | NTR285 |
| Other | : N/A |
| ISRCTN | ISRCTN13667534 |

# Study results

**Summary results**
N/A