

Intrauterine pressure monitoring for augmentation or induction of labour with intravenous oxytocin: benefits and costs

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/01/2010	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR285

Study information

Scientific Title

To evaluate the effectiveness of the use of an IntraUterine Pressure Catheter (IUPC) in comparison to external monitoring of uterine activity during (I) augmentation after arrest of labor, or (II) induction of labour with intravenous oxytocin. Does the potentially more accurate monitoring of uterine activity with IUPC lead to a better outcome of labour and delivery in a study that randomises the use of an IUPC?

Acronym

The IUPC study

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre, randomised, single-blind, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Pregnancy, labour

Interventions

Intrauterine pressure monitoring with a catheter during labour versus external uterine activity monitoring (control group).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Oxytocin

Primary outcome measure

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

Secondary outcome measures

1. The occurrence of neonatal admittance to Neonatal Intensive Care Unit (NICU)
2. Need for antibiotics by mother or child
3. Total amount of oxytocin used
4. Complications
5. Time to delivery and costs

Overall study start date

01/07/2004

Completion date

01/07/2007

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

1350

Key exclusion criteria

1. Women with a history of caesarean section
2. Gestational age less than 36 weeks
3. Intrauterine foetal death
4. Breech presentation
5. Multiple pregnancy
6. Maternal age greater than 18 years
7. Human immunodeficiency virus (HIV) or hepatitis B infection

8. Intrauterine infection
9. Contraindication for amniotomy
10. Participation in another randomised controlled trial

Date of first enrolment

01/07/2004

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

Sponsor details

Department of Obstetrics and Gynaecology

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor type

Hospital/treatment centre

Website

<http://www.amc.uva.nl/>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/01/2010		Yes	No