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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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
29/01/2010

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

Results and Publications

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