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A randomised, multicentre, open label trial comparing the start of the induction of labour with intravenous oxytocin according to the circadian rhythm with standard care

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
15/07/2021

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised, multicentre, open label trial comparing the start of the induction of labour with intravenous oxytocin according to the circadian rhythm with standard care

Acronym
Dauwtrappen of Nachtbraken

Study objectives
Our hypothesis is that induction of labour with intravenous oxytocin starting in the evening, following the circadian rhythm, shortens the duration of labour compared to a start in the early morning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Induction of labour with intravenous oxytocin

Interventions
The women who start with induction of labour in the evening (21:00 hours) are defined as the intervention group. The control group are those women who start in the early morning (07:00 hours).

Both groups are treated by the exactly the same protocol, except for the timing of the start of induction.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Oxytocin

Primary outcome measure
The definition of the primary outcome is the duration of labour in minutes:
1. For the on protocol analysis in the final analysis of the trial, the duration of labour is defined as the time measured from start of the drip until time of birth of the baby, in case of twins the time of the first baby
2. For intention to treat analysis, the duration of labour is defined as the time of occupation of the labor room

Secondary outcome measures
1. Number of interventions like ventouse, forcipal extraction and caesarean section
2. Number of children with an Apgar score below 7 after 5 minutes
3. Number of intrapartum infections
4. Necessity for pain relief and use of morphine, pethidine or epidural anaesthesia
5. Patient satisfaction with quality of care

Overall study start date
01/11/2003

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Women are eligible to participate when the clinician judges that it is favourable to induce labour and the cervix is favourable for induction with a drip of oxytocin.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
400

Total final enrolment

371

Key exclusion criteria
1. Intrauterine foetal death
2. Maternal age below 18 years
3. Insufficient understanding of the meaning of the trial
4. Language problems
5. Contraindication for amniotomy
6. Secondary caesarean section in the medical history
7. Gestational age shorter than 36 weeks
8. Necessity for timed or immediate intervention because of suspected foetal distress

Date of first enrolment
01/11/2003

Date of final enrolment
01/01/2006

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
Meibergdreef 9
Amsterdam
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1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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		01/03/2009	15/07/2021	Yes	No