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

No registrations found.

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

Summary

ID

NL-OMON22012

Source
NTR

Brief title
Dauwtrappen of Nachtbraken

Health condition

Induction of labor with intravenous oxytocin.

Sponsors and support

Primary sponsor: AMC:J.J.H. Bakker, Dr.J.A.M. van der Post, Dr.R. de Vos.
OLVG: Dr.J.M.M.van Lith
SLVZ:Drs.A.J.van Veelen
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The definition of the primary outcome is the duration of labor in minutes.
For the on protocol analysis in the final analysis of the trial, the duration of labor 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.

For intention to treat analysis, the duration of labor is defined as the time of occupation of the labor room.

Secondary outcome

Secondary outcomes are the number of interventions like ventouse, forcipal extraction and caesarean section, number of children with an Apgar score below 7 after 5 minutes, number of intrapartum infections, necessity for pain relief and use of morphine, pethidine or epidural anaesthesia, and the patient satisfaction with quality of care.

Study description

Background summary

Induction of labor is a common intervention in obstetrics.
In the Netherlands in around 23 percent of the women that were referred to the gynaecologist is induced. Labor is induced when pregnancy must end before the spontaneous onset of labor, usually because of increasing risks for mother or child caused by for example maternal illness like hypertension, preeclampsia, diabetes, prolonged pregnancy, prelabor rupture of the membranes > than 24 hours. When the cervix seems favourable, amniotomy is performed and oxytocin in a drip is started and administered in an increasing dose until regular uterine contractions occur with a frequency of three to four contractions every ten minutes. In most hospitals these elective inductions start in the early morning.

The spontaneous onset of labor however is proven to have a circadian rhythm with a preferential start of labor in the evening.
When labor begins with contractions in the evening the total duration of labor and delivery shortens, and in addition less obstetrical interventions occur. The biological explanation for this phenomenon is that the myometrium of the uterus is more sensitive for maternal oxytocin in the night than in the daytime. There is good reason to believe that the results found in spontaneous labor may also count for induced labor using intravenous oxytocin.
To our knowledge there is no study investigating this hypothesis. This study investigates therefore whether induction with intravenous oxytocin starting in the evening, following the circadian rhythm, shortens the duration of labor compared to a start in the early morning and evaluates the impact on medical interventions, the condition of the child, intrapartum

infections, the necessity for pain relief and the patient satisfaction with the quality of care.

Study objective

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

Study design

N/A

Intervention

The women who start with induction of labor 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.

Contacts

Public
Academic Medical Center (AMC),
Department of Obstetrics and Gynaecology,
H3-107,
P.O. Box 22660
J.J.H. Bakker
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111
Scientific
Academic Medical Center (AMC),
Department of Obstetrics and Gynaecology,
H3-107,
P.O. Box 22660
J.J.H. Bakker
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Excluded are women with:

1. Intrauterine fetal 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 fetal distress.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2003
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion

Date:	05-08-2005
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	NL81
NTR-old	NTR112
Other	: N/A
ISRCTN	ISRCTN52897947

Study results

Summary results

N/A