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.

Gepubliceerd: 05-08-2005 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22012

Bron
NTR

Verkorte titel
Dauwtrappen of Nachtbraken

Aandoening

Induction of labor with intravenous oxytocin.

Ondersteuning

Primaire 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
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2003
Aantal proefpersonen:	400
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL81
NTR-old	NTR112
Ander register	: N/A
ISRCTN	ISRCTN52897947

Resultaten

Samenvatting resultaten

N/A