

# 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

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/07/2021	<b>Condition category</b> 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

## 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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **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)

## ROR

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

# Funder(s)

## Funder type

Not defined

## Funder Name

Not provided at time of registration

# 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?
<a href="#">Results article</a>		01/03/2009	15/07/2021	Yes	No