

Obstetric analgesia: a comparison of patient controlled Pethidine, Remifentanil and Fentanyl in labour.

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The hypothesis of this study is that the new opioid remifentanil will provide less side-effects and better painrelief during labour, than the conventional opioids fentanyl and pethidine.

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

Samenvatting

ID

NL-OMON29457

Bron

NTR

Verkorte titel

baringspijn

Aandoening

labourpain

Ondersteuning

Primaire sponsor: Bronovo hospital,
Department of Obstetrics and Gynaecology, The Hague

Overige ondersteuning: Researchfonds Bronovo, Bronovo hospital, The Hague

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Quality of pain relief determined by Visual Analogue Scale, PCA demands/rewards and the number of parturients crossing over to epidural analgesia;

2. Patient satisfaction;

3. Fetal Outcome as determined by Apgar, NACS and requirement for naloxone;

4. Presence of opioid substances in umbilical and maternal blood samples.

Toelichting onderzoek

Achtergrond van het onderzoek

Obstetric analgesia: A comparison of patient controlled pethidine, remifentanil and fentanyl in labour.

Background:

There is great need for new analgesic methods during labour. The purpose of this study is to compare a relatively new agent, remifentanil, with two conventional analgesics, pethidine and fentanyl.

Remifentanil is characterized by a rapid onset of action and short latency to its peak effect. The elimination half-time ranges from 8 to 20 minutes. There is no accumulation of the drug during repeat bolus injection. These characteristics make remifentanil very suitable for administration via patient controlled analgesia (PCA), which can be used for analgesia during labour.

Objective:

The main objective of this study is to compare the analgesic efficacy and safety of remifentanil, pethidine and fentanyl during labour, when all are administered as patient-controlled analgesia.

Outcome parameters are:

1. Quality of pain relief as determined by Visual Analogue Scale, PCA demands/rewards and number of parturients crossing over to epidural analgesia;

2. Patient Satisfaction;
3. Fetal Outcome as determined by Apgar, NACS and requirement for naloxone;
4. Presence of opioid substances in umbilical cord and maternal blood samples.

Study design:

This study will be a double-blind randomized controlled clinical trial and will evaluate three different analgesic drugs during labour. All drugs will be administered using a PCA device.

Population:

Women in an early, but active stage of labour (with minimum dilation cervical of 3 cm), who make a request for analgesia. The planned sample size is around 240 patients.

Drugs/dosages:

The following drugs are used in a patient controlled method:

Drug Loading Dose

Dosage/bolus Lockout timeMax. Total Dosage

Remifentanil - 40 µg 2 min. 1200 µg/h

Pethidine 50 mg 5 mg 10 min. 200 mg

Fentanyl 50 µg 20 µg 5 min. 240 µg/h

Load on patient and risks involved with the research.

Baseline non-invasive measurements will be made, including maternal blood pressure, heart rate, respiratory rate and pulse oximetry. Measurements will be recorded every 30 minutes. Also, an observer sedation score will be recorded every 30 min. Fetal heart rate and uterine activity will be recorded by external monitoring. Pain scores will be assessed every hour using a visual analogue scale. Satisfaction scores, sedation scores and anxiety scores will be assessed in the same way. These scores will also be recorded hourly. After delivery, there will be taken a maternal and an umbilical cord blood sample in order to determine opioid serum concentration.

All opioids have similar side effects. Most important in this research is the possibility of respiratory depression. In order to monitor the occurrence of side effects and reduce risks to the patient the progress will continuously be monitored by the medical students executing the research protocol (in collaboration with attending gynaecologist).

Doel van het onderzoek

The hypothesis of this study is that the new opioid remifentanil will provide less side-effects and better painrelief during labour, than the conventional opioids fentanyl and pethidine.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

The following drugs are used in a patient controlled method:

1. Pethidine;
2. Remifentanil;
3. Fentanyl.

Medication will be started in active labour en will be continued untill complete dilation of the cervix is achieved.

Contactpersonen

Publiek

Leiden University Medical Center
Department of Anesthesiology
P.O. Box 9600

M.R. Douma
Leiden 2300 RC
The Netherlands
0031 (0)6 14276591

Wetenschappelijk

Leiden University Medical Center
Department of Anesthesiology
P.O. Box 9600

M.R. Douma

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age: at least 18 years old;
2. Between 37 and 42 weeks of gestation;
3. ASA physical status I or II.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. ASA physical status $\geq$ III;
2. Obesity (BMI equal or more than 40 kg/m²);
3. Substance abuse history;
4. High risk patients: including pre-eclampsia (diastolic pressure equal or more than 100, proteinuria), hepatic insufficiency or renal failure, severe asthma, poorly controlled diabetes mellitus);
5. Premature labour;
6. Drug allergy; history of hypersensitivity to opioid substances.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	10-08-2005
Aantal proefpersonen:	180
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	04-12-2005
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	NL501
NTR-old	NTR543
Ander register	: N/A
ISRCTN	ISRCTN12122492

Resultaten

Samenvatting resultaten

N/A