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

No registrations found.

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

Summary

ID

NL-OMON29457

Source
NTR

Brief title
baringspijn

Health condition

labourpain

Sponsors and support

Primary sponsor: Bronovo hospital,
Department of Obstetrics and Gynaecology, The Hague
Source(s) of monetary or material Support: Reseachfonds Bronovo, Bronovo hospital, The Hague

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

N/A

Study description

Background summary

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 ìg 2 min. 1200 ìg/h
Pethidine 50 mg 5 mg 10 min. 200 mg
Fentanyl 50 ìg 20 ìg 5 min. 240 ìg/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. Satifaction 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).

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age: at least 18 years old;

2. Between 37 and 42 weeks of gestation;

3. ASA physical status I or II.

Exclusion criteria

1. ASA physical status >= 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2005
Enrollment:	180
Type:	Actual

Ethics review

Positive opinion

Date:	04-12-2005
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	NL501
NTR-old	NTR543
Other	: N/A
ISRCTN	ISRCTN12122492

Study results

Summary results
N/A