Differences in maternal temperature and saturation after administration of remifentanil PCA or epidural analgesia during labor

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29662

Source
NTR

Brief title
N/A

Health condition

labor pain, labour pain, saturation, temperature, epidural analgesia, remifentanil
baringspijn, saturatie, temperatuur, epiduraal

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

Intervention

Outcome measures

Primary outcome

Main objective is to compare the side effects of remifentanil PCA with those of epidural analgesia. The evaluation will be based upon the following parameters:

1. maternal temperature

2. maternal saturation

Secondary outcome

The secondary objective:

To compare other known side effects, in particular;

- nausea

- pruritus

- sedation

- hypotension

Fetal oucome as determined by:
- Apgar scores

- umbilical cord pH

- NACS

- requirement naloxone

Study description

Background summary

Introduction

Epidural analgesia is considered to be the best form of pain relief during labor. However its use has been associated with an increase of maternal temperature. This can lead to unnecessary administration of antibiotics during labor and observation and treatment for sepsis of neonates.
A relatively new option for obstetric analgesia is remifentanil PCA. Possible adverse effects of remifentanil resemble those of other opioids and include hypotension and respiratory depression.

Hypothesis

Epidural analgesia leads to a higher incidence of maternal fever as compared to patients receiving remifentanil PCA or no analgesia.

Maternal saturation scores are lower in parturients receiving remifentanil PCA compared to patients receiving epidural analgesia or no analgesia.

Objective

The main objective of this study is to compare the side effects of remifentanil, administered intravenous patient-controlled, with those of epidural analgesia.
The evaluation will be based upon the following outcome parameters:

• Maternal temperature

• Maternal saturation

Secondary Objective

• To compare the incidences of other known side effects, in particular nausea, pruritus, sedation and hypotension.

• Fetal outcome as determined by Apgar scores, umbilical cord pH, NACS and requirement for naloxone.

Methods

One hundred and seventy-five parturients will be recruited. Patients requesting analgesia will be randomized to receive either remifentanil PCA or epidural analgesia. Parturients receiving no analgesia will form the control group.
Maternal bloodpressure, heart rate, saturation and temperature will be measured at regular intervals. Painscores will be assessed using a visual analogue scale.

Fetal heart rate and uterine activity will be measured continuously. At delivery neonatal outcome including Apgar scores at 1 and 5 minutes, cord blood gas analysis and the Neurologic and Adaptive Capacity Score (NACS) will be recorded.

Poweranalysis

A total population of 175 patients is needed for this trial.

Study objective

1. Epidural analgesia leads to a higher frequency of maternal fever as compared to patients receiving remifentanil PCA or no analgesia.

2. Maternal saturation scores are lower in parturients receiving remifentanil PCA compared to patients receiving epidural analgesia or no analgesia.

Study design

- Maternal bloodpressure, heart rate, saturation and temperature will be measured at regular intervals.

- Fetal heart rate and uterine activity will be measured continuously.

- At delivery neonatal outcome including Apgar scores at 1 and 5 minutes, cord blood gas analysis and the Neurologic and Adaptive Capacity Score (NACS) will be recorded.

Intervention

All patients will enter the study in a control group (group with no analgesia). Patients requesting analgesia, will be randomized to one of two study groups:

1. remifentanil patient controlled analgesia

2. epidural analgesia

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18 years and older

2. Between 24-42 weeks of gestation

3. ASA I or II

Exclusion criteria

1. Prior administration of regional or opioid analgesia (during this delivery)

2. Morbid obesity (BMI > 40kg/m2)

3. Drug allergy: history of hypersensitivity to opioid or local anesthetic substances

4. Severe pre-eclampsia (proteinuria > 5 grams)

5. Use of antibiotics during delivery

6. Initial maternal SpO2 of less than 98%

7. Initial maternal temperature of 38 C or higher

8. Cervical dilation of > 7cm

9. Ruptured membranes for more than 24 hours at time of inclusion

10. Contraindication for epidural analgesia

Study design

Design

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

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2008
Enrollment:	175
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-10-2008
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	NL1437
NTR-old	NTR1498
Other	: P08.092
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results