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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29662

Bron
NTR

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: Leiden University Medical Center (LUMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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.

Onderzoeksproduct en/of interventie

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

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
Leiden 2300 RC
The Netherlands
0031 (0)6 14276591

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18 years and older

2. Between 24-42 weeks of gestation

3. ASA I or II

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2008
Aantal proefpersonen:	175
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-10-2008
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	NL1437
NTR-old	NTR1498
Ander register	: P08.092
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten