A comparison of remifentanil patient-controlled analgesia with epidural analgesia during labor.

No registrations found.

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

Summary

ID

NL-OMON27184

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Laborpain.

Sponsors and support

Primary sponsor: Leiden University Medical Centre.
Source(s) of monetary or material Support: Sponsor.

Intervention

Outcome measures

Primary outcome

1. Quality of pain relief as determined by Visual Analogue Scale scores;

2. Patient satisfaction;

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

Secondary outcome

N/A

Study description

Background summary

Purpose of this study is to compare the analgesic efficacy and safety of remifentanil, administered as patient-controlled analgesia, with epidural analgesia.

Objective:

1. Quality of pain relief as determined by Visual Analogue Scale scores;

2. Patient satisfaction;

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

Methods: 20 patients. One group will receive remifentanil patient controlled analgesia (bolus 40 microgram. lockout 2 min). The other group will receive epidural analgesia (ropivacaine/sufentanil). Analgesia will be admininsterd throughout the first stage of labor. Baseline non-invasive measurements will be made at regular intervals. Pain and satisfaction scores will be assessed using a visual analogue scale (VAS). Fetal heart rate will be measured and scored as reactive or non reactive. Observations for known side effects will be made. At delivery Apgarscore, bloodgas analysis and NACS will be recorded.

Study objective

The hypothesis is that epidural analgesia will provide better painrelief during labor with less side-effects than remifentanil.

Study design

N/A

Intervention

1. 10 patients will receive remifentanil patient controlled analgesia;

2. 10 patients will receive epidural analgesia;

Medication will be started in active labor and will be continued untill full dilation of the cervix is achieved.

Contacts

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

M.R. Douma
Leiden 2300 RC
The Netherlands
0031 (0)6 14276591
Scientific
Leiden University Medical Center
Department of Anesthesiology
P.O. Box 9600

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

Eligibility criteria

Inclusion criteria

1. Age ? 18 years;

2. Between 37 and 42 weeks of gestation;

3. Singleton pregnancy;

4. ASA physical status I or II.

Exclusion criteria

1. ASA physical status ? III;

2. Morbid obesity (BMI ? 40 kg/m2);

3. Substance abuse history;

4. High risk patients: including pre-eclampsia (diastolic pressure ? 100 mmHg, proteinuria), severe asthma (daily use of medication), insulin dependent diabetes mellitus, hepatic insufficiency or renal failure;

5. Premature labor;

6. Drug allergy; history of hypersensitivity to opioid or local anesthetic substances;

7. Cervical dilation >5cm.

Study design

Design

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

Control: Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2007
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion

Date:	17-11-2007

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	NL1094
NTR-old	NTR1127
Other	: P07.120
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A