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

Published: 28-05-2008
Last updated: 11-05-2024

The main objective of this study is to compare changes in maternal temperature and oxygen saturation in patients receiving remifentanil, administered intravenous patient-controlled, with those of epidural analgesia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON32311

Source
ToetsingOnline

Brief title
maternal temperature and oxygen saturation during delivery

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
labor pain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: epidural analgesia, intrapartum fever, remifentanil, saturation

Outcome measures

Primary outcome

* Maternal temperature

* Maternal saturation

Secondary outcome

* 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.

Study description

Background summary

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:
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 objective

The main objective of this study is to compare changes in maternal temperature and oxygen saturation in patients receiving remifentanil, administered intravenous patient-controlled, with those of epidural analgesia.

Study design

This study will be a prospective randomized controlled trial and will evaluate differences in maternal saturation and temperature in parturients receiving either remifentanil PCA or epidural analgesia.

Intervention

Remifentanil group: 40microgram boluses, lockout time 2 min. Maximum dose limit is 1200 microgram/hour.

Epidural group: ropivacaine plus sufentanil.
Loading dose 25 mg (12.5 ml ropivacaine 0.2%), followed by continuous infusion of ropivacaine 0.1%/sufentanil 0.5 microgram/ml.
Infusion rate 10 ml/hour.
In case of inadequate analgesia, additional boluses of the epidural solution will be given.

Study burden and risks

Pulse and saturation will be monitored continuously by means of a Nonin WristOx pulsoximeter.
Maternal bloodpressure, temperature and respiratory rate will be recorded hourly.
In patients receiving epidural analgesia or remifentanil PCA, measurements of bloodpressure and respiratory rate will be recorded every 5 minutes for the fist 30 minutes, and every hour afterwards.

Painscores will be assessed using a visual analogue scale every hour. After delivery patients will be asked to give an overall satisfaction score

Fetal heart rate and uterine activity will be monitored continuously by external monitoring and if necessary by invasive monitoring.

In patients receiving epidural analgesia, motor block of the lower limbs will be assessed.

Adverse effects of analgesics used in this study include hypotension, nausea and rarely respiratory depression. For savety reasons, there will be a observer in the delivery suite all times providing continuous monitoring.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age *18 years
* Between 37-42 weeks of gestation
* Singleton pregnancy
* ASA physical status I or II

Exclusion criteria

* Prior administration of regional of opioid analgesia (during this delivery).
* Morbid obesity (BMI * 40 kg/m2)
* Drug allergy: history of hypersensitivity to opioid or local anesthetic substances
* High risk pregnancy: including severe asthma (daily use of medication), insulin dependent

diabetes, severe pre-eclampsia (proteinuria * 5 grams)
* Use of antibiotics during delivery
* Initial maternal SpO2 of less than 98%
* Initial maternal temperature of 38°C or higher.
* Cervical dilation of > 7 cm
* Ruptured membranes for more than 24 hours at time of inclusion
* Contraindication for epidural analgesia

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2008
Enrollment:	175
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ultiva
Generic name:	remifentanil
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	28-05-2008
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
EudraCT	EUCTR2008-002792-28-NL
CCMO	NL23193.058.08