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

Gepubliceerd: 17-11-2007 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27184

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Laborpain.

Ondersteuning

Primaire sponsor: Leiden University Medical Centre.
Overige ondersteuning: Sponsor.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

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;

2. Between 37 and 42 weeks of gestation;

3. Singleton pregnancy;

4. ASA physical status I or II.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Controle: Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	26-11-2007
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	17-11-2007
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	NL1094
NTR-old	NTR1127
Ander register	: P07.120
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A