Postoperatieve pijnbehandeling middels continue epidurale toediening van bupivacaïne/sufentanil versus bupivacaïne/morfine bij patiënten na een grote chirurgische ingreep.

Gepubliceerd: 11-01-2009 Laatst bijgewerkt: 19-03-2025

Hypothesis to be tested (null hypothesis): A continuous epidural infusion of bupivacaïne/sufentanil is equal to bupivacaïne/morphine in patients undergoing major surgery in terms of analgesia and side effects.

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

Samenvatting

ID

NL-OMON22506

Bron
NTR

Verkorte titel
BUPISUF

Aandoening

epidural, bupivacaïne, sufentanil, morphine, analgesia, side effects
Epiduraal, morfine, analgesie, bijwerkingen

Ondersteuning

Primaire sponsor: UMCU
Overige ondersteuning: UMCU

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The pain scores during the first 72 hours after surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

Postoperative analgesia with continuous epidural bupivacaine/sufentanil versus bupivacaine/morphine in patients undergoing major surgery is compared in a double blind randomised clinical trial. The patients are randomised to either bupivacaïne 2.5 mg/ml + morphine 0.08 mg/ml or bupivacaïne 2.5 mg/ml + sufentanil 1 ug/ml. Primary outcome is the pain score on a Numerical Rating Scale (NRS) during the first 72 hours after surgery. Side-effects (pruritus, nausea and vomiting) and adverse effects (respiratory depression, sedation and motor block) are also recorded.

Doel van het onderzoek

Hypothesis to be tested (null hypothesis):

A continuous epidural infusion of bupivacaïne/sufentanil is equal to bupivacaïne/morphine in patients undergoing major surgery in terms of analgesia and side effects.

Onderzoeksopzet

The adequacy of analgesia will be assessed every 30 minutes in the recovery room and every hour during the first 4 hours postoperative and every 8 hours the next 72 hours. The quality of pain relief will be classified daily .

Onderzoeksproduct en/of interventie

Patients are randomly assigned in two treatment groups:

1. Bupivacaïne 2.5 mg/ml + morphine 0.08 mg/ml (group BM);

2. Bupivacaïne 2.5 mg/ml + sufentanil 1 ug/ml (group BS).

Before surgery a epidural catheter is inserted. After surgery patients are receiving either continuous epidural bupivacaïne with morphine (BM) 4-6 ml/hr or bupivacaïne with sufentanil (BS) 4-6 ml/hr. Both groups receive usual care, only the epidural mixture medication is different. Subjects will be not be allowed to see the study medication.

During the postoperative course residents from the department anaesthesiology adjust the infusion rate of the study medication once a day to the individual patient's requirement. The aim is to achieve a pain score of 4 or less and a dynamic pain score of 6 or less. Patients in both groups are permitted to take paracetamol and/or NSAIDS's at any time during the study.

If there is any doubt concerning the correct position of the epidural catheter 4-6 ml lidocaïne 2% will be administered according to the protocol. If an adequate analgesic effect can not be achieved in the first 8 hours after the end of the operation, the patient is excluded from the trial.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18 years or older;

2. Scheduled major surgery;

3. Indication for epidural catheter according to the responsible anaesthesiologist.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with an allergy to one of the study medications;

2. Patients using opioids pre-operatively;

3. Patients who are not speaking Dutch;

4. Patients with mental disability;

5. Pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	424
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-01-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33682
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL684
NTR-old	NTR1622
CCMO	NL19432.041.09
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON33682

Resultaten

Samenvatting resultaten
N/A