

# Postoperative analgesia with continuous epidural bupivacaine/sufentanil versus bupivacaine/morphine in patients undergoing major surgery.

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33682

### Source

ToetsingOnline

### Brief title

bupisuf

### Condition

- Other condition

### Synonym

analgesia

### Health condition

pijnbehandeling

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

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

## Intervention

**Keyword:** Analgesia, Epidural, Opioids, Postoperative

## Outcome measures

### Primary outcome

-The pain scores of the patient on the Numerical Rating Scale (NRS) during the first 72 hours after surgery.

### Secondary outcome

-Registration of side-effects: pruritus, nausea and vomiting.  
-Registration of adverse effects: respiratory depression, sedation and motor block.  
-The quality of pain relief by the patient.

## Study description

### Background summary

Epidural analgesia is an effective method of pain relief after major cardiothoracic, upper abdominal, urogenital and lower limb surgery. Continuous epidural analgesia can be effectuated by different medication. There is no evidence indicating the optimal medication or mixture. Frequently used mixtures are bupivacaine with morphine, sufentanil or fentanyl. In our hospital we use bupivacaine 2,5 mg/ml with morphine 0.08 mg/ml, 4-8 ml/h. In a pilot study, we have evaluated 448 consecutive patients treated with this mixture epidurally. Twenty four hours after surgery 36% of the patients had moderate and severe

pain (VAS > 4), 12% had severe pain (VAS > 7), all measured on movement. 24.3% of the 448 patients complained of nausea, 8% of these patients actually vomited. Pruritus occurred in 29.5% of the patients. Compared to Brodner et al [3] and to Tuncel et al the presented pain scores are rather high and side-effects are frequent. Therefore, the question arises whether the postoperative care can be improved by replacing morphine into sufentanil. Although many studies on postoperative pain have been performed, continuous epidural bupivacaine with morphine or sufentanil have not been compared in a large, prospective, randomised study.

#### Reference:

Kavanagh B, Katz J, Sandier A. Pain control after thoracic surgery. A review of current techniques. *Anesthesiology* 1994; 81: 737-59.

Dijk van J. Continuous epidural analgesia with bupivacaine and morphine after major surgery in 2006: pain and side effects. Study not published.

Brodner G, Mertes N, Van Aken H, et al. What concentration of sufentanil should be combined with ropivacaine 0.2% wt/vol for postoperative patient-controlled epidural analgesia? *Anesthesia and Analgesia* 2000; 90: 649-57.

Tuncel G, Ozalp G, Savli S, et al. Epidural ropivacaine or sufentanil-ropivacaine infusions for post-thoracotomy pain. *European Journal of Cardio-thoracic Surgery* 2005; 28: 375-9.

Broekema A, Gielen M and Hennis P. Postoperative analgesia with continuous epidural sufentanil and bupivacaine: a prospective study in 614 patients. *Regional Anesthesia and Pain Management* 1996; 82: 754-9.

### **Study objective**

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

The aim of the study is to compare the analgesic efficacy and side-effects of a continuous epidural infusion of bupivacaine/sufentanil and bupivacaine/morphine mixture in patients undergoing major surgery.

Continuous epidural analgesia can be effectuated by different medication.

There is no evidence indicating the optimal medication or mixture.

In our hospital we use bupivacaine/morphine, other possible mixtures are bupivacaine/sufenta or bupivacaine/fentanyl.

Theoretically bupivacaine/sufenta is probably the best choice and is the used most elsewhere.

The purpose of this study is to compare the analgesic efficacy and side-effects of a continuous epidural infusion of bupivacaine/sufentanil or bupivacaine/morphine mixture in patients undergoing major surgery.

## Study design

This study is a monocenter, double-blinded, randomised controlled clinical trial.

## Intervention

Interventions: group BM: bupivacaïne 2.5 mg/ml + morphine 0.08 mg/ml  
group BS: bupivacaïne 2.5 mg/ml + sufentanil 1 ug/ml

## Study burden and risks

Not different from conventional treatment.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

All patients > - 18 years old, scheduled for major surgery and indicated for epidural catheter.

## Exclusion criteria

No dutch speaking, mental disability, allergy to one of the study medications. Pregnancy.

## Study design

### Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2010
Enrollment:	530
Type:	Actual

### Medical products/devices used

Product type:	Medicine
Brand name:	sufenta
Generic name:	sufentanil
Registration:	Yes - NL intended use

## Ethics review

Approved WMO

Date: 20-04-2009

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 25-08-2009

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 22506

Source: NTR

Title:

### In other registers

Register	ID
EudraCT	EUCTR2007-005275-33-NL
CCMO	NL19432.041.09
OMON	NL-OMON22506