The haemodynamic effects of spinal anaesthesia with versus without sufentanil added to bupivacaine heavy

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Will spinal anaesthesia with sufentanil and bupivacaine heavy cause less hypotension compared to bupivacaine heavy alone? Will there be less use of ephedrine/fenylefrine/noradrenaline if sufentanil is added to bupivacaine heavy for spinal...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Interventional

Summary

ID

NL-OMON42723

Source
ToetsingOnline

Brief title
Spinal study

Condition

- Therapeutic procedures and supportive care NEC

Synonym
Spinal anaesthesia

Research involving
Human

Sponsors and support

Primary sponsor: Sint Lucas andreas Ziekenhuis
Source(s) of monetary or material Support: Onderzoek wordt vrijwillig uitgevoerd door onderzoeker;aangezien het standaard behandelingen betreft zal de medicaite geen extra

kosten met zich meebrengen.

Intervention

Keyword: Haemodynamics, Local anaestheticum, Opioid, Spinal

Outcome measures

Primary outcome

Haemodynamic change: percentage blood pressure and MAP decrease from baseline blood pressure in holding and in the operation room. Total amount of ephedrine/fenylefrine/noradrenaline used to correct blood pressure and MAP.

Secondary outcome

Comparing postoperative pain and side effects between both groups; including nausea, vomiting, pruritus and dizziness .

Study description

Background summary

One of the side effects of intrathecal local anaesthetics is hypotension, caused by sympathetic blockade. The addition of various doses of opioids may allow the dose of local anaesthetic to be reduced, producing a synergistic effect that enhances analgesia, prolongs the duration of the spinal block and it can be hypothesized that without an increase in degree of sympathetic blockade it might cause less hypotension compared to administration of a local anaesthetic alone.

Study objective

Will spinal anaesthesia with sufentanil and bupivacaine heavy cause less hypotension compared to bupivacaine heavy alone? Will there be less use of ephedrine/fenylefrine/noradrenaline if sufentanil is added to bupivacaine heavy for spinal anaesthesia compared to bupivacaine heavy alone?

Study design

Double blind randomized controlled trial

Intervention

Patients in the study group will receive bupivacaine heavy 2 ml (10mg) plus 1 ml sufentanil (5mcg).
Patients in the control group will receive bupivacaine heavy 3 ml (15 mg) without the addition of sufentanil.

Study burden and risks

Two standard treatments will be compared with each other.
The extra burden for the patients are 7 questions postoperatively in the recovery room and the patient has to fill in a questionnaire of 7 questions on the ward

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Patients undergoing surgery with spinal anaesthesia.
ASA I-III
18-90 years old

Exclusion criteria

- ASA IV-V patients
- Patients younger than 18 years or older than 90 years;Contra-indication for spinal anaesthesia:*
**Severe aortic valve stenosis or severe heart disease
- Local infection at puncture site
- Allergy for local anaesthetics or opioids

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-08-2017
Enrollment:	300
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Marcaine heavy 0,5%

Generic name:	Bupivacaine heavy 0,5%
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Sufenta
Generic name:	Sufentanil
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	14-09-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-09-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2015-002843-32-NL
CCMO	NL54015.100.15