A comparison of the efficacy of levobupivacaine 0,125%, ropivacaine 0,125% and ropivacaine 0,2%, all combined with sufentanil 0.5 micrograms/mL, in patient-controlled epidural analgesia after hysterectomy under combined epidural and general anesthesia

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to compare the analgesic efficacy of levobupivacaine and ropivacaine in patient-controlled epidural analgesia, as assessed by the number of requests for epidural bolus injectionsto compare visual analogue scale (VAS) scores and neural block...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON30436

Source
ToetsingOnline

Brief title
levobupi 0,125%,ropiv 0,125% and 0,2%,with sufenta 0.5 microgr/mL, in PCEA

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
hysterectomy, removal of uterus

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: eigen budget

Intervention

Keyword: epidural, levobupivacaine, PCEA analgesia, ropivacaine

Outcome measures

Primary outcome

*Number of requests of patient-controlled 2 mL boluses (granted and refused)

*Visual analogue scale (100 mm) scores for resting pain at T = 6, 12, 24 and 48

hours

*Motor block (0-12) scores for the lower extremities motor blockade at T = 6,

12, 24 and 48 hours

*Level of sensory blockade (number of dermatomes) at T = 6, 12, 24, and 48

hours (thermal sensation)

*Systolic and diastolic blood pressure, heart rate, mixed venous oxygen

saturation by pulse-oximetry and respiratory rate at T = 6, 12, 24,and 48 hours

*Time of removal of the epidural catheter

*Incidence of nausea, pruritus, hypotension or sedation

*Overall patient satisfaction with pain treatment (scale 1-10)

Secondary outcome

none

Study description

Background summary

In a recently completed study (protocol nr. P04.038) we compared the efficacy of ropivacaine 0.2 %, ropivacaine 0.125 % and levobupivacaine 0.125 %, all in combination with sufentanil 1 *g / mL, in terms of epidural pain relief after total knee replacement (21). Under the conditions of this study we found that sufentanil was the primary determinant of postoperative pain relief and that increasing the concentration of local anesthetic (0.2 % versus 0.125 %) increased the consumption of local anesthetic without increasing the intensity of pain relief

Study objective

to compare the analgesic efficacy of levobupivacaine and ropivacaine in patient-controlled epidural analgesia, as assessed by the number of requests for epidural bolus injections
to compare visual analogue scale (VAS) scores and neural block characteristics (level of sensory blockade and degrees of motor block) and hemodynamic data between the three study groups
to compare the incidences of side effects, in particular nausea, pruritus, hypotension and sedation

Study design

It is a randomisend, prospective and double blinded study

Intervention

epidural analgesia with levobupivacaine 0,125% or ropivacaine 0, 125% or ropivacaine 0,2% all in combination with sufentanil 0,5 microgram/ml.

Study burden and risks

During the study period there will be four times a short interview and neurological investigation. Time taken will be 10 minutes each.

Contacts

Public
Academisch Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL
Scientific
Academisch 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

*Female patient >18 years
*ASA class I-III
*Patients undergoing abdominal hysterectomy under combined epidural and general anesthesia
*Written informed consent

Exclusion criteria

*Participation in a trial on investigational drugs within 3 months prior to the study
*Known hypersensitivity to amide-type local anesthetics
*Known hypersensitivity to opioids
*Known history of severe cardiovascular, hepatic, renal, respiratory, endocrinological, haematological, neurological or psychiatric disease as judged by the investigator
*Known history of peripheral neuropathies
*Those receiving chronic analgesic therapy
*Any contraindication for epidural analgesia (e.g. clotting disorders, history of lumbar surgery)

*Inability to perform VAS score
*Pregnancy or lactation
*Any other reason which in the opinion of the investigator makes the patient unsuitable for participation in the study

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):	05-11-2007
Enrollment:	63
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	chirocaine
Generic name:	levobupivacaine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	naropin
Generic name:	ropivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-05-2007
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	EUCTR2007-000202-75-NL
CCMO	NL16230.058.07