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Analgesic and anaesthetic effects of spinal opioid added to local anaesthetic for perioperative management of minor anorectal surgery

Submission date
23/07/2024

Recruitment status
No longer recruiting

Registration date
04/10/2024

Overall study status
Completed

Last Edited
02/10/2024

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The study focuses on adult patients admitted for minor anorectal surgery, agreeing to participate in the study and experience spinal anaesthesia either with one medication or a combination of two medications. The aim is to provide an adequate level, duration and quality of anaesthesia by reduction of the dose of local anaesthetic and addition of a low dose of spinal opioid.

Who can participate?
Adult patients aged 18 and more years admitted for minor anorectal surgery and giving signed informed consent for spinal anesthesia can participate in the study.

What does the study involve?
The characteristics of spinal anaesthesia including levels of sensory and motor blocks, sensation of pain, duration of analgesia and resolution from spinal anaesthesia will be evaluated from the very start of anaesthesia to patient discharge. The quality of spinal anaesthesia will be assessed by the patient in the operating room and before discharge and by the medical staff in the operating room and in the surgical ward on a 0-2 point scale where 0 is described as unacceptable, 1 - intermediate quality of service and 2 - excellent level of service, would choose the same anaesthesia again.

What are the possible benefits and risks of participating?
Participants enrolled in the study will gain additional attention of the medical staff, more frequent visits to the ward. In case of unpleasant sensations they will receive adequate treatment.

Where is the study run from?
Hospital of the Lithuanian University of Health Sciences Kaunas Clinics is managing the study.

When is the study starting and how long is it expected to run for?
October 2003 to December 2008

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
75/2003

Study information

Scientific Title
Spinal anaesthesia with 4 mg versus 3 mg of hyperbaric bupivacaine plus 10 µg of fentanyl for adult anorectal surgery: faster recovery with prolonged analgesia

Study objectives
The goal of study was to test the hypothesis that addition of fentanyl to low-dose spinal hyperbaric bupivacaine reduces the effective dose of bupivacaine with faster recovery and similar quality of anaesthesia for anorectal surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/10/2003, Kaunas Regional Biomedical Research Ethics Committee (A. Mickevičiaus St. 9, Kaunas, LT44307, Lithuania; +370 61483823; kaunorbtek@lsmu.lt), ref: 75/2003

Study design
Prospective randomized double-blinded

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Available in Lithuanian (native language of patients).

Health condition(s) or problem(s) studied
Sensory, motor and analgesic effects of spinal anesthesia

Interventions
Patients are allocated randomly to one of two groups using sealed envelopes: Group S3F (n = 65) receive 3 mg (0.6 ml) of spinal 0.5 % hyperbaric bupivacaine along with 10 µg (0.2 ml) to a total

volume of 0.8 ml, while Group S4 received 4 mg (0.8 ml) of spinal 0.5 % hyperbaric bupivacaine. Patients are familiarised with the visual analogue pain scale (VAS) of 0-100 mm and anaesthesia quality scale.
Spinal anaesthesia is induced in the sitting position, with a 26 G spinal needle, using a median approach. The dura is punctured at L3-4 or L4-5 and hyperbaric bupivacaine (Marcaine Spinal Heavy 0.5 %) injected over 2 minutes: Group S4 0.8 ml, Group S3F 0.6 ml + fentanyl 10 µg to 0.8 ml as stated by the envelope. After sitting for 10 minutes, patients are instructed to lie down. Level of the sensory block is tested with an alcohol swab. Motor block is tested using a modified Bromage scale (0 = no motor block, 1 = able to flex ankle and bend knees, 2 = able to flex ankle, 3 = full motor block). After this, surgery is started. In case of unsuccessful block, supplementary fentanyl or sedation with thiopentone are administered.
After the surgery, the surgical ward nurse is responsible for postoperative assessment according to postoperative protocol. Morphine is administered in increments of 2.5 – 5 mg if VAS pain score was > 50, until VAS ≤ 30.
The following variables are assessed: demographics (age, gender, type of surgery), duration of anaesthesia (from dural puncture until patient left the operating room), duration of surgery, rate of success (failed block), level and duration of sensory (dermatomes) and motor (according to Bromage scale) block 10 minutes after dural puncture, at the end of surgery, in postoperative ward every 30 minutes until full resolution of the block, time to voiding and ambulation, complications (including pruritus, urinary retention on 0 – 2 scale, where 0 = normal urination, 1 = difficult spontaneous urination, 2 = unable to urinate and catheterisation was required), consumption of analgesics during surgery and postoperatively, level of pain (VAS scale 0-100) measured at 1.5, 2, 2.5, 3, 6, 9, 12, 18 and 24 h postoperatively, quality of anaesthesia according to the patient and medical staff (0 – 2 scores).

Intervention Type
Drug

Pharmaceutical study type(s)
Dose response

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fentanyl, hyperbaric bupivacaine

Primary outcome measure
Duration of sensory block is regarded as the primary variable. Level and duration of sensory block is measured using dermatomes and alcohol swab at 10 min after dural puncture and, at the end of surgery, in postoperative ward every 30 minutes until full resolution of the block.

Secondary outcome measures
1. Demographics using patient records (age, gender, type of surgery) at patient arrival.
2. Duration of anaesthesia measured using time record at time from dural puncture until patient left the operating room.
3. Duration of surgery measured using time record from the start to the end of surgery.
4. Rate of success and failed block determined as the ability to make a dural puncture at the start of anaesthesia.
5. Level and duration of motor block measured using Bromage scale at 10 minutes after dural puncture, at the end of surgery, in postoperative ward every 30 minutes until full resolution of

the block.
6. Time to voiding measured using time record at the moment of first postoperative urination.
7. Time to ambulation measured using time record at the time of the patient's ability to walk without assistance.
8. The rate of postoperative complications measured using patient complaints and recovery records: pruritus measured as patient complaint after resolution of the spinal block; urinary retention measured using patient complaints and recovery records on 0-2 point scale (where 0 = normal urination, 1 = difficult spontaneous urination, 2 = unable to urinate and catheterisation is required) at patient discharge.
9. Level of pain using VAS scale 0-100 at 1.5, 2, 2.5, 3, 6, 9, 12, 18 and 24 h postoperatively at rest and movement.
10. Consumption of analgesics measured counting the total doses of opioid and non-opioid analgesics consumed over 24 h postoperatively.
11. Quality of anaesthesia according to the patient and medical staff is measured using a scale of 0 – 2 scores at patient discharge from the operating room (surgeon and anaesthesiologist) and at patient discharge from the hospital (surgical ward nurse, patient).
12. Data collection is continued until patient discharge or until 24 h postoperatively and is stopped at 24 h after surgery.

Overall study start date
20/10/2003

Completion date
20/12/2008

Eligibility

Key inclusion criteria
Adult consecutive patients admitted for elective minor anorectal surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
62 patients in both groups (total 124 patients).

Total final enrolment
132

Key exclusion criteria
1. ASA physical scale greater than 3
2. Body mass index (BMI) exceeding 30 kg/m²
3. Unfit for spinal anaesthesia
4. Under chronic use of psychotropic or analgesic medications
5. Unwilling to participate

Date of first enrolment
15/12/2005

Date of final enrolment
15/12/2008

Locations

Countries of recruitment
Lithuania

Study participating centre
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
http://lsmuni.lt/en/

ROR

https://ror.org/0069bkg23

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
30/12/2024

Individual participant data (IPD) sharing plan
The data is stored in a non-publicly available repository and will be available under request. Contact Jurate Gudaityte jurate.gudaityte@kaunoklinikos.lt

IPD sharing plan summary
Stored in non-publicly available repository, Available on request