ISRCTN31685121 https://doi.org/10.1186/ISRCTN31685121

To compare the pain relief from combined intrathecal bupivacaine-morphine with bupivacaine alone in lower limb surgery

Submission date
25/04/2022

Recruitment status
No longer recruiting

Registration date
12/05/2022

Overall study status
Completed

Last Edited
05/05/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Inadequate pain medication during and after surgery may lead to long term pain after surgery.

This study was designed to ascertain the effect of morphine addition to bupivacaine in the management of postoperative pain in patients undergoing lower limb surgeries at the Tamale Teaching Hospital, Ghana.

Who can participate?
Patients aged 16 – 60 years, undergoing lower limb surgery.

What does the study involve?
Participants will be randomly allocated to receive bupivicane alone or bupivicane plus morphine during surgery. Follow up lasts 72 hours.

What are the possible benefits and risks of participating?
Benefits: There were no immediate benefits for participation in the study. No gifts or money were given in exchange for the information obtained. However, data generated from this study will help policy makers in the Ministry of Health to improve the management of postoperative pain after Orthopaedic and Trauma surgeries.
Risks: Participants were informed that they may experience slight pain during the sample collection process. Should they suffer any injury during the collection process, members of the research team will take full responsibility and cover all expenses pertaining to treatment.

Where is the study run from?
Tamale Teaching Hospital, Ghana.

When is the study starting and how long is it expected to run for?
April 2021 to November 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

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Scientific

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Study information

Scientific Title
Analgesic efficiency of intrathecal bupivacaine with morphine and bupivacaine alone in lower limb orthopaedic surgery. A comparative study

Acronym

IBM

Study objectives
Bupivacaine with morphine induces better postoperative pain relief and improve patient outcomes in lower limb orthopaedic surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/09/2021, Ethical review board of the Kwame Nkrumah University of Science and Technology (University Post Office, Kumasi, Ghana; +233(0)205453785; chrpe@knust.edu.gh), ref: CHRPE/AP/416/21

Primary study design
Interventional

Study design
Randomised comparative controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Postoperative pain management in trauma patients

Interventions
After meeting the inclusion criteria, eligible patients received 15 mg preservative free hyperbaric bupivacaine and 0.2 mg morphine or 15 mg bupivacaine alone. Patients were followed up 72 hrs for postoperative complications and patient outcome.
Each recruited patient was randomly assigned to one of two groups using a computer-generated random number table. Group A (n=30) represented those who received bupivacaine alone and Group B (n=30) represented those who received bupivacaine with morphine.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
bupivacaine, morphine

Primary outcome(s)
1. Vital signs (pulse rate, blood pressure, oxygen saturation, and respiratory rate) of the patient were monitored and recorded for every 5 minutes for the first 30 minutes and then for every 15 minutes during surgery
2. Pain severity was measured every 4 hours for 72 hours immediately after the surgery on a 100-mm VAS, 0 mm = no pain, and 100 mm = intolerable pain.

Key secondary outcome(s)

1. The episodes of postoperative nausea and vomiting (PONV) were identified by direct scheduled assessments or by a spontaneous complaint by the patients after the surgery. The incidence of PONV was recorded hourly for the first 4 hours and then 4 hourly for the next 24 hours using a 3 point ordinal scale (0 = none, 1 = nausea, 2 = vomiting). The incidence of PONV was calculated and categorized as early (0 – 4 hours) or delayed (5 – 24hours).
2. The incidence of pruritus was recorded every 4 hours for 48 hours after surgery on a four-point categorical scale as; 0 = no pruritus, 1 = mild, 2 = moderate, 3 = severe pruritus.
3. Overall perioperative satisfaction was evaluated on the day of discharged during an interview as; 4 = excellent, 3 = good, 2 = satisfactory, 1 = poor.

Completion date
30/11/2021

Eligibility

Key inclusion criteria
1. Patients undergoing elective lower limb orthopaedic surgery
2. ASA status class I and II
3. Patients between 16 - 60 years of age
4. Patients who were on admission for 72 hours or more postoperatively

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Pregnant or breastfeeding mothers
2. Patients with polytrauma
3. Glasgow coma scale <15
4. Opioids abusers
5. Expected post-surgical stay <24 hours
6. ASA physical status class III and IV
7. Patients allergic to bupivacaine and/morphine
8. Contraindication to spinal anaesthesia

Date of first enrolment
10/09/2021

Date of final enrolment

29/11/2021

Locations

Countries of recruitment
Ghana

Study participating centre
Tamale Teaching Hospital
Box 1350TL
Tamale
Ghana
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Sponsor information

Organisation
Platinum Orthopaedic and Spine Clinic

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Availability of data and materials: The datasets generated and/or analysed during the current study are not publicly available due to patient confidentiality but are available from the corresponding author on reasonable request.
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IPD sharing plan summary
Available on request