

Pain control with spinal morphine combined with spinal anesthesia before orthopedic surgery

Submission date 25/03/2018	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 16/05/2018	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 24/04/2019	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Pain management in El Salvador is underestimated; thousands of patients suffer intense pain after surgery, without any adequate protocol for painkillers (analgesics) based on intensity. Among Latin American countries, morphine sulfate is the painkiller with the lowest consumption rate for pain management, exposing the breach of patient's right for pain relief. This study aims to determine the effectiveness and safety of combining painkiller medication (multimodal analgesia) using preventative doses, combined with pain control after surgery.

Who can participate?

Adults aged 18 or over undergoing elective orthopedic surgery requiring spinal anesthesia

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive two painkillers (spinal morphine and bupivacaine) in combination prior to surgery. Those in the second group only receive one (bupivacaine). After surgery, all participants receive one drug (Ketorolac) to reduce swelling (anti-inflammatory). They are followed up for 24 hours, rating pain with a verbal scale and administered an appropriate drug for pain level based on guidance from the World Health Organisation.

What are the possible benefits and risks of participating?

Participants may potentially benefit from pain control in the first 24 hours after surgery, with individualized pain assessment and treatment. There is no monetary gain for participation in the study. Participants may be at risk of experiencing itchiness, difficulty urinating, nausea, vomiting and in very rare cases difficulty breathing.

Where is the study run from?

San Rafael Hospital (El Salvador)

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

June 2014 – November 2014

Who is funding the study?
Dr. Jose Matias Delgado University, affiliate of San Rafael Hospital (El Salvador)

Who is the main contact?
Dr Carlos Salazar (Scientific)
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Additional identifiers

Protocol serial number

Study information

Scientific Title

Multimodal analgesia using 100 µg of preemptive intrathecal morphine sulfate combined with hyperbaric bupivacaine for postoperative pain control in orthopedic surgery: a double blind randomized clinical trial

Study objectives

Multimodal analgesia using a single dose of preemptive intrathecal morphine sulfate added to hyperbaric bupivacaine for spinal anesthesia is more effective compared to postoperative opioid and non-opioid pain control after orthopedic surgery

Ethics approval required

Old ethics approval format

Ethics approval(s)

San Rafael Hospital Investigation Ethics Committee, 26/06/2013, ref: 4570

Study design

Phase IV single center double blind randomized clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pain control

Interventions

Participants are randomly allocated to the experimental group or control. Those in the experimental group (M1) receive 100 µg of intrathecal morphine sulfate combined with 1-2 mL of hyperbaric bupivacaine for spinal anesthesia on the preoperative setting. The control group (M0) receive 1-2 mL of hyperbaric bupivacaine alone.

Both groups (M1) and (M0) receive 30 mg of Ketorolac I.V. for anti-inflammatory effect on the time of discharge from the recovery room, and they are followed up to 24 hours in the orthopedic department, evaluating episodes of pain intensity with Verbal Numerical Rating Scale (VNRS) and administering for every single pain episode a dose of Paracetamol 500-1000 mg PO, Tramadol 50 mg PO, Ketorolac 30 mg I.V. or 60 mg I.M., Diclofenac 75 mg I.M. or Meperidine 50 mg I.V. based on WHO's analgesic ladder.

Intervention Type

Drug

Phase

Phase IV

Primary outcome(s)

Pain is assessed by the following:

- 1.1. Individual interviews before discharge from the Post-Anesthesia Care Unit (baseline) and every single episode of pain during the first 24 hour post-operative period
- 1.2. Time to appearance of first episode of pain in the 24 hour post-operative period
- 1.3. Intensity of pain was measured using the verbal numeric rating scale (VNRS)
- 1.4. Frequency of pain episodes is measured throughout the 24 hour post-operative period

Key secondary outcome(s)

1. Type and quantity of analgesics needed is measured according the WHO's analgesic ladder throughout the 24 hour post operative period
2. Frequency of episodes of pruritus, nausea and vomiting, respiratory depression, and urinary retention are measured throughout the 24 hour post operative period
3. Patient satisfaction is evaluated using using a questionnaire based on the Likert scale in the first 24 hours

Completion date

28/11/2014

Eligibility**Key inclusion criteria**

1. 18 years and older
2. ASA I and II
3. Lower limb fracture
4. Elective orthopedic surgery
5. Spinal anesthesia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. <18 years-old
2. ASA > II
3. Documented allergy to opioids or non opioid analgesics
4. Emergency surgery
5. BMI >35
6. Asthma

- 7. Obstructive sleep apnea
- 8. Chronic use of opioids defined as more than > 2 weeks
- 9. Pregnancy
- 10. History of drug abuse or alcohol use
- 11. History of psychiatric condition

Date of first enrolment

01/04/2014

Date of final enrolment

15/10/2014

Locations

Countries of recruitment

El Salvador

Study participating centre

San Rafael Hospital

Santa Tecla

El Salvador

0000

Sponsor information

Organisation

San Rafael Hospital

Funder(s)

Funder type

University/education

Funder Name

Dr. Jose Matias Delgado University

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Carlos Salazar, csalaz8@uic.edu

Additional documentation:

Protocol available at: <http://www.redicces.org.sv/jspui/handle/10972/1879>

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1	14/05/2018	17/05/2018	No	Yes