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

**Submission date**
25/03/2018

**Recruitment status**
No longer recruiting

**Registration date**
16/05/2018

**Overall study status**
Completed

**Last Edited**
24/04/2019

**Condition category**
Musculoskeletal Diseases

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] 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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# Contact information

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Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
PH7

# 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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
See additional file

### 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 administrating 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 measure
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

### Secondary outcome measures
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

### Overall study start date
15/01/2013

### 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

### Age group

Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
80 patients

### 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

### Sponsor details
Carr. Panamericana 15
Santa Tecla
El Salvador
0000

### Sponsor type
Hospital/treatment centre

## Funder(s)

### Funder type
University/education

### Funder Name
Dr. Jose Matias Delgado University

## Results and Publications

### Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

### Intention to publish date
10/05/2019

### 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 |