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The effect of magnesium sulfate on recurrence of rebound pain in patients undergoing regional anesthesia in the arm

Submission date
25/11/2022

Recruitment status
No longer recruiting

Registration date
22/12/2022

Overall study status
Completed

Last Edited
20/12/2022

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
Peripherical nerve blocks provide effective analgesia for long durations, and lower opioid intake, nausea and vomiting, resulting in faster hospital discharge. But some patients might experience intense pain after the effects of regional anesthesia, known as rebound pain. There are medicines when mixed with local anesthetics can provide better results, such as dexmedetomidine, dexamethasone, and magnesium sulfate. The study aims to evaluate the rebound pain with and without magnesium sulfate as an adjuvant with ropivacaine in supraclavicular brachial plexus nerve block in upper limb surgeries. Our hypothesis is that magnesium sulfate as a perineural adjuvant could reduce the incidence of rebound pain, improving patients postoperative pain control.

Who can participate?
Adults over the age of 18, submitted to surgeries of the distal arm, forearm, and hand, eligible to supraclavicular brachial plexus nerve block and sedation, in Mario Covas State Hospital in Santo Andre, Sao Paulo.

What does the study involve?
Participants are asked to join this study while they wait in the room for nursing triage before their surgery. Participants must understand the anesthesia process and the diary of pain they will complete in the following 24h after the surgery. Participants are randomly allocated to one of two groups. Those in the first group will receive an adjuvant mixed with the local anesthetic. Those in the second group will receive local anesthetic only. Both groups will fill in scores of pain on the diary of pain in the next 24h and note the need for opioids, in the search for better pain scores.

What are the possible benefits and risks of participating?
The possible benefit to those taking part is lower pain scores after surgery and less opioid intake. The main risk is block failure, others like pneumothorax, blood bruises, and nerve damage are also in consideration, all of them diminished by the usage of ultrassonography-guided puncture.

Where is the study run from?
The study is being run by the ABC Foundation and takes place in Mario Covas State Hospital in Santo Andre, Sao Paulo (Brazil)

When is the study starting and how long is it expected to run for?
April 2021 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The impact of perineural magnesium sulfate on rebound pain after supraclavicular brachial plexus block - randomized clinical trial

Study objectives
The use of magnesium sulfate as a perineural adjuvant could reduce the incidence of rebound pain, improving postoperative pain control in patients undergoing upper limb surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/08/2022, College of Medicine of ABC Research Ethics Committee (2000 Lauro Gomes avenue, Santo André, SP; +55(11)49935453; cep@fmabc.br), ref: 5.582.819.

Study design
Interventional double-blinded randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Prevention of rebound pain in patients undergoing supraclavicular brachial plexus block for upper limb surgery.

Interventions
The sample size was calculated using STATA/IC v.17 (StataCorp, College Station, TX, USA) and also considering previous studies and potential exclusions from the protocols. The sample is 34, with 17 participants each group.
The participants are randomized to group A (saline) and group B (magnesium sulfate) using Research Electronic Data Capture, REDCap® v. 10.
The participants and researchers are blinded to the intervention.

The solution is prepared by an independent assistant according to the solution preparation guide:
Group A: One syringe of 20mL with 0.5% of ropivacaine.

Preparation: aspirate 10mL of 1% ropivacaine [100mg] and 10mL of 0.9% saline solution with a 20mL syringe.
Group B: One syringe of 20mL with 0.5% ropivacaine and 1% magnesium sulfate.
Preparation: aspirate 10mL of 1% ropivacaine [100mg] with a 20mL syringe. After, add 2mL of 10% magnesium sulfate [200mg] and 8mL of 0.9% saline solution in the same syringe.

The syringes and their contents are indistinguishable for both groups to mask solutions.
The location of the supraclavicular brachial plexus will done in real time with ultrasound linear probe and with peripheral nerve stimulator connected to needle (Stimuplex® A 30° B Braun 50mm, 22 Gauge short bevel).
The bevel tip of the needle will positioned towards the angle formed by the first rib and the subclavian artery, called the "corner pocket". Then, an electrical current with an intensity of 0.3 mA, frequency of 2Hz and pulse width of 0.1ms will activated. After that, the stimulation of the structures innervated by the ulnar nerve being expected. Afterwards, 10mL of anesthetic solution will administered in the absence of resistance.
Next, the needle will repositioned until the main neural cluster formed by the superior and middle trunks. In this place, 10mL of the anesthetic solution will add without resistance.

The sensory and motor block are checked for up to 45 minutes. In case of total or partial failure of anesthesia after that time, the block are considered not viable for the surgical procedure.
If there are no contraindications, Ondansetron 8mg, Ketoprofen 100mg, Pantoprazole 40mg and Dipyrone 2 grams will administered intravenously 40 minutes before the surgical incision for both groups.
At hospital discharge, the participants will responsible for completing the Visual Numeric Scale (VNS) in the pain diary by the first 24 hours after the block. All participants will receive a phone call 24 hours after the block as part of routine care and to collect clinical relevant data.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Magnesium sulfate, ropivacaine hydrochloride.

Primary outcome measure
1. Pain measured by the Visual Numerical Scale (VNS) every 6 hours after the block for 24 hours
2. The time of block resolution, considered as the time when the first rescue analgesia was taken. However, in cases that didn't require rescue analgesia, the time of block resolution will be considered when the patient reports the end of numbness or the end of heaviness in the blocked region.

Secondary outcome measures
Average cumulative opioid consumption in milligrams between the groups in the first 24 hours after the block, according to the doses taken and checked in the medical prescription.

Overall study start date
27/04/2021

Completion date

31/12/2023

Eligibility

Key inclusion criteria
1. Patients with ASA Physical Status classification I-lll;
2. Ability to understand and complete the pain diary;
3. Patients undergoing arm, forearm and hand surgery with indication for supraclavicular brachial plexus block without the association of another regional block or general anesthesia.

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
34

Key exclusion criteria
1. Severe heart disease;
2. Decompensated kidney disease;
3. Decompensated liver disease;
4. Severe respiratory failure;
5. Cognitive dysfunction that prevents cooperation with the study;
6. Calcium channel blocker treatment;
7. Confirmed coagulopathy;
8. Infection at the procedure location;
9. Illicit drug used 5 days ago;
10. Daily use of opioids more than 14 days before surgery;
11. Block failure;
12. Need to send to the intensive care unit (ICU) in the immediate postoperative period;
13. Neuropathy in the upper limb to be operated;
14. Allergy to local anesthetic, propofol or non-steroidal anti-inflammatory drugs;
15. Weight <50 Kilograms (kg);
16. Body mass index (BMI) > 35 kg/m²;
17. Chronic pain;
18. Pregnancy;
19. Need to change the anesthetic technique intraoperatively.

Date of first enrolment
01/10/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
Brazil

Study participating centre
Mario Covas State Hospital
321 Dr Henrique Calderazzo St, Paradise
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Sponsor information

Organisation
The Committee for Ethics in Research (CEP) in ABC's Foundation

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Sponsor type
University/education

Website
http://www.fmabc.br/comite-de-etica

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Marcela Marçolla Tavares by the e-mail address: marcelamarcolla@hotmail.com.
All the data will become available after the scientific article is published during 5 years.
Data will be stored for 5 years after publication of the results in a scientific journal. Datasets will be available to identified researchers upon request who are interested in scientific research. After shared, they can be analyzed by all types of statistical mechanisms according to the researcher's interest.
The recorded data are anonymous, there are no ethical restrictions and were/will be collected after the consent signed by the research participant.

IPD sharing plan summary
Available on request