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Efficacy of two local anaesthetic preparations with different sodium content, in sciatic nerve block for "hallux valgus" (bunion) surgery

Submission date
29/08/2015

Recruitment status
No longer recruiting

Registration date
04/09/2015

Overall study status
Completed

Last Edited
04/09/2015

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
Hallux vulgaris, more commonly known as a bunion, is a bony deformity of the joint at the base of the big toe at the side of the foot. Although some people never experience any symptoms, many people suffer for years with bunions, as pressure from shoes against it can cause pain and discomfort. An operation to correct the deformity may be offered, if non-surgical treatments do not cause any relief. In order to numb the foot so that the surgery can be performed, an anaesthetic is injected into the main nerve that supplies the foot (popliteal sciatic nerve block). Commonly, the local drug mepivacaine is used for this procedure, because it works and wears off more quickly than other drugs used. Studies have shown that the amount of sodium (salt) in the anaesthetic dilution can affect how good it is at providing pain relief, as sodium plays a key role in nerve signals. The aim of this study is to find out whether the amount of sodium in the mepivacaine has an effect in a popliteal sciatic nerve block.

Who can participate?
Adults without a life-threatening condition who are scheduled for surgery to correct a bunion (Chevron Osteotomy for Hallux Vallgus).

What does the study involve?
An ultrasound-guided sciatic nerve block at popliteal (above knee) level is performed on all participants. The participants are then randomly allocated into two groups by a computer. Participants in the first group receive 1.5% mepivacaine with the normal solution, and participants in the other group receive a dilution containing 5% dextrose and a lower sodium content. Participants are asked how well they feel that the anaesthetic worked 24 hours after surgery. Whether there has been any loss of movement or sensation in the foot is measured at 24 hours, 48 hours and one week after the surgery.

What are the possible benefits and risks of participating?
Participating in the study does not directly benefit patients; however it will help to increase knowledge of the best techniques to use. There are no significant risks of participating, as both dilutions of mepivacaine are used in routine clinical practice and are safe for patients. There are

general risks associated with anaesthesia and nerve blocks, but patients will be closely monitored to avoid these.

Where is the study run from?
La Paz University Hospital (Spain)

When is the study starting and how long is it expected to run for?
April 2013 to February 2014

Who is funding the study?
La Paz University Hospital (Spain)

Who is the main contact?
Dr Mercedes López

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HULP code: 3839

Study information

Scientific Title
Comparison of two solutions of 1.5% mepivacaine with different sodium concentrations for ultrasound guided popliteal block. A randomised controlled trial

Study objectives

A dilution of 1.5% mepivacaine made with 5% dextrose, instead of our normal dilution with 1% and 2% mepivacaine, thus decreasing sodium content in a 30%, would make decrease the required volume of LA for a complete sensory block, in the case of an ultrasound (US) guided popliteal sciatic nerve block in patients undergoing unilateral elective “hallux valgus” repair surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee and clinical research, CEIC, “La Paz” University Hospital, 21/03/2013, ref: 3839

Study design
A randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Hallux valgus (bunion)

Interventions
Mepivacaine, at a concentration of 1.5%, was administered for all the popliteal blocks in both groups. In the normal dilution group, the dilution was made with 1% and 2% mepivacaine. In the D5 group, dilution was made with 2% mepivacaine and 5% dextrose. In the first patient of both groups, the volume administered was 25 ml. The volumes received by the subsequent patients were determined by the response of the previous patient of the same group (success or failure), following the "up-and-down" allocation technique. If the previous patient had acquired a complete sensory block, the next patient of the same group had the volume of 1.5% mepivacaine decreased by 1ml, and increased by 1 ml if the block had failed in the previous patient. An anaesthesiologist, who did not know the volume or dilution used in the patient, evaluated the sensory and motor blocks. Sensory and motor blocks were assessed after 5 minutes of the time 0, and every 5 minutes until the two blocks were complete, or up to 30 minutes after the blockade. A telephone interview was conducted 24 hours after the procedure, by a researcher who had not been present during it, to document side effects such as sensory loss, paraesthesias, or any other complication derived from the blockade. The patient was also asked about time for block resolution (sensitivity and mobility of the foot). If the patient did not report at that time any side effect, they would not be assessed any further. If instead the patient referred some sequel, he/she was asked to come to the hospital to be assessed personally by a specialist. If the deficit was diagnosed, the patient was reassessed 48 hours and a week after the

surgery. If the deficit persisted one week after the block performance, the patient would have been referred to the multidisciplinary chronic pain unit of the hospital for monitoring and treatment.

Intervention Type
Other

Primary outcome measure
Complete sensory blockade in popliteal territory after 30 minutes of the puncture (YES/NO). With the sequence of complete and incomplete blockades the effective dose is calculated in 50% of patients (ED50) of 1.5% mepivacaine that provides complete sensory ultrasound-guided block of the sciatic nerve with a popliteal approach in both groups, following the "up-and-down" allocation technique described by Dixon.

Secondary outcome measures
1. ED90 and ED95 of 1.5% mepivacaine in both groups
2. Need for an extra dose of local anaesthetic through the catheter before or during surgery (YES /NO)
3. Need for sedation (YES/NO) and/or general anaesthesia (YES/NO) during surgery
4. Presence of any adverse events related to the puncture (YES/NO). If yes, note what kind of event
5. Time to recover the normal sensation and movement of the foot (it was asked to the patient 24 hours after the puncture)
6. Patient satisfaction (on a scale from 1 to 10) at 24 hours after the puncture
7. Existence of paraesthesias, sensory, or motor deficit in the foot at 24, 48 hours and 1 week after the puncture

Overall study start date
04/04/2013

Completion date
28/02/2014

Eligibility

Key inclusion criteria
1. Patients scheduled for unilateral "hallux valgus" surgery repair by osteotomy of the first metatarsal type "chevron", and intended to be operated by the same surgical team
2. Age between 18 and 80 years
3. Physical status ASA I-III
4. Body mass index (BMI) less than 35 kg / m2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Existence of any regional anaesthesia contraindication
2. Inability to distinguish the popliteal nerve with ultrasound
3. Cognitive impairment
4. Chronic use of opioids and/or neuroleptic drugs
5. Pregnancy
6. Peripheral neuropathy
7. Patients less than 18 years old or more than 80
8. ASA IV classification
9. Allergy to drugs used in the study
10. Body mass index (BMI) ≥ 35 kg/m2.

Date of first enrolment
04/04/2013

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
Spain

Study participating centre
La Paz University Hospital
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Sponsor information

Organisation
La Paz University Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01s1q0w69

Funder(s)

Funder type
University/education

Funder Name
La Paz University Hospital

Results and Publications

Publication and dissemination plan
The study will be submitted to the journal Anaesthesia and Intensive Care.

Intention to publish date
31/10/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request