ISRCTN55964940 https://doi.org/10.1186/ISRCTN55964940

A study to see whether we can increase the pain-free period in upper limb surgeries with regional anaesthesia block by adding dexmedetomidine to low-dose levobupivacaine

Submission date
27/10/2021

Recruitment status
No longer recruiting

Registration date
15/11/2021

Overall study status
Completed

Last Edited
29/11/2022

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether it is possible to reduce pain after upper limb surgery by adding dexmeditomedine to levobupivacaine in upper limb anaesthesia blocks.

Who can participate?
Patients aged 18-60 years who are undergoing upper limb surgery

What does the study involve?
Participants are randomly allocated to one of two groups. One group is given a nerve block with levobupivacaine and the other group is given levobupivacaine with dexmedetomidine. The onset time and duration of sensory and motor blockade and the time to first rescue pain relief are all recorded.

What are the possible benefits and risks of participating?
Participants may benefit from reduced pain after surgery.

Where is the study run from?
Bangalore Medical College and Research Institute (India)

When is the study starting and how long is it expected to run for?
October 2017 to September 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Vijayakumar HN
viji2751977@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Vijayakumar H N

Contact details
Department of Anaesthesia
Victoria Hospital
Bangalore Medical College and Research Institute, FORT
Bangalore
India
560002
+91 (0)9886504680
drhnv@yahoo.com

Additional identifiers

Study information

Scientific Title
A comparative study of the effect of 0.25% levobupivacaine in ultrasound-guided supraclavicular brachial plexus block

Acronym
Dexlevo

Study objectives
Dexmeditomidine increases the onset and duration of motor and sensory block and duration of analgesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/02/2018, Bangalore Medical College and Research Institute (Fort, Bangalore, Karnataka, 56002, India; +91 (0)80-26700810; director_bmcri@yahoo.co.in), ref: BMC/PGs/303 /2017-18

Primary study design
Interventional

Study design
Double-blind randomized trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Elective upper limb surgery

Interventions
60 ASA I and II patients aged between 18 to 60 years of either sex undergoing elective upper limb surgery lasting more than 30 minutes were included in the study. They were divided into two groups of 30 each in a randomised double-blind method. The patients underwent supraclavicular brachial plexus block under ultrasound guidance. Group L was given a nerve block with 20 ml of 0.25% levobupivacaine and 1 ml saline and group D received 20 ml of 0.25% levobupivacaine with 0.5 mcg/kg of dexmedetomidine (diluted to a volume of 1 ml). Onset time and duration of sensory and motor blockade and time to first rescue analgesia and hemodynamic variations were recorded.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexmeditomidine, levobupivacaine

Primary outcome(s)
1. Sensory block assessed by atraumatic pinprick test using a three-point scale at 3, 6, 12, 15, 18, 21, 24, 27, 30 min
2. Motor block assessed using the Modified Bromage three-point scale at 5, 10, 15, 20, 25 and 30 min, and thereafter every 15 min for 2 h and then 30 min until the block effect has resolved
3. Sedation score assessed by the Ramsay sedation scale at 0, 5, 10, 15, 20, 25, 30 min
4. Pain assessed using a visual analogue scale (VAS) 0-10 at 0, 5, 10, 15, 20, 30 min, then hourly for 24 hours

Key secondary outcome(s)
1. Duration of analgesia measured using visual analogue scale hourly until the patient complains of pain over 24 h
2. Adverse events measured including hypotension, bradycardia, drop-in saturation, recorded by continuous monitoring for 24 h

Completion date
16/09/2019

Eligibility

Key inclusion criteria
1. Undergoing elective upper limb surgery lasting more than 30 minutes
2. Aged 18-60 years
3. American Society of Anesthesiologists Classification (ASA) I and II

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Hypertension
2. Uncontrolled diabetes
3. Arrhythmia
4. Renal failure
5. Liver failure
6. Bleeding tendencies
7. Pregnant
8. Neuropathy

Date of first enrolment
20/02/2018

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
India

Study participating centre
Bangalore Medical College and Research Institute
Fort
Kalasipalya
Bangalore
India
560002

Sponsor information

Organisation
Bangalore Medical College and Research Institute

ROR
https://ror.org/05qmk4a18

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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 Dr Vijayakumar HN (drhnv@yahoo.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/03/2022	29/11/2022	Yes	No