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# 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
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Vijayakumar H N

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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
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

## Study design
Double-blind randomized trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
No participant information sheet available

## 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 measure
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

### Secondary outcome measures
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

### Overall study start date
01/10/2017

### 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

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
60 Years

### Sex
Both

### Target number of participants
60

### 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
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India
560002

## Sponsor information

### Organisation
Bangalore Medical College and Research Institute

### Sponsor details
Kalasipalya, Fort
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### Sponsor type
Research organisation

### Website
http://www.bmcri.org/

### ROR
https://ror.org/05qmk4a18

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

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

**Intention to publish date**
30/12/2021

**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 |