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The effect of dexmedetomidine in addition to local anaesthetic on the block of nerves in the arm

Submission date
15/12/2011

Recruitment status
No longer recruiting

Registration date
10/02/2012

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Axillary brachial plexus block is a regional anesthestic technique that is sometimes used as an alternative or in addition to general anesthetic for surgery on the arm or hand. The aim of this study is to investigate the effects of adding the pain medication dexmedetomidine to local anaesthetic levobupivacaine in axillary brachial plexus block.

Who can participate?
Patients aged 18-60 scheduled for forearm and hand surgery under axillary block

What does the study involve?
Participants are randomly allocated into two groups: one group are treated with levobupivacaine and the other group are treated with levobupivacaine and dexmedetomidine. Demographical data, blood pressure, heart rate, oxygen levels, sensory and motor block onset times and block durations, time to first painkiller use, total painkiller need and side effects are recorded for each patient.

What are the possible benefits and risks of participating?
It is hoped that dexmedetomidine will prolong the duration of anesthesia and pain relief with a shorter onset time.

Where is the study run from?
Cumhuriyet University (Turkey)

When is the study starting and how long is it expected to run for?
November 2011 to February 2012

Who is funding the study?
Investigator initiated and funded (Turkey)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of dexmedetomidine addition to levobupivacaine in axillary brachial plexus blockade

Study objectives
In this study the aim is to investigate the effects of dexmedetomidine addition to levobupivacaine in axillary brachial plexus block. It is hypothesized that dexmedetomidine addition will prolong the duration of anesthesia and analgesia with a shorter onset time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cumhuriyet University Ethics Committee, 04/04/2007, ref: 2007-4/4

Study design

Randomized controlled double-blind prospective trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Anaesthesia and analgesia in the arm

Interventions
The patients were randomly divided into two groups:
Group L (n=32): Levobupivacaine (Chirocaine, 5 mg/mL; Abbott Lab/Turkey) with isotonic sodium chloride
Group D (n=32): Levobupivacaine and dexmedetomidine (Precedex 200 mcg / 2 mL, Meditera, Turkey) with isotonic sodium chloride
The randomization was achieved by random number table. The drug solutions were prepared by an anesthesiologist who was not involved in the study.

The patients were monitored for their mean arterial blood pressures (MAP), heart rate (HR), and peripheral oxygen saturation (SpO2) in the operation room before the blockage and baseline values were recorded. All patients were not given any premedications. After insertion of a 20-gauge intravenous (IV) catheter in a peripheral vein in the contralateral arm, axillary block was performed with the patient in the supine position and the upper arm with 90° abduction and the elbow with 110° flexion. During the application, a nerve stimulator (Stimuplex, Braun, Germany) was used for the nerve localization. For blockage, 22G, 50 mm stimulating needle (Stimuplex D, B.Braun Melsungen AG, Japan) was used. The stimulator was adjusted to 1.0 mA, 2 Hz, 0.1 ms parameters at the beginning of the procedure. The location of the needle was accepted adequate when an output current < 0.5 mA caused a slight distal motor response. After the localization of radial, ulnar, median and musculocutaneous nerves, group L (n=32) patients were given a total 40 mL solution of 39 mL levobupivacaine 0.5% with 1 mL of isotonic sodium chloride solution, and group D (n=32) patients were given a total 40mL solution of 39 mL levobupivacaine 0.5% with 1 mL volume of 1 µg kg-1 dexmedetomidine plus isotonic sodium chloride solution in a double-blind mode. A multi-stimulation technique was used in all of the patients of both groups. Anesthetic mixture (10 mL for each nerve = 40 mL) were injected after identifying the radial, ulnar, median and musculocutaneous nerves in each patient. During injection, negative aspiration was performed every 3.04.0 ml to avoid intravascular injection. If there was any blockade failure in a nerve distribution region, even if the block was adequate for the surgery, the patients were excluded from the study. All axillary brachial plexus blocks were performed by the same anesthesiologist.

Sensory and motor blockades of median, radial, ulnar, and musculocutaneous nerves, and HR, MAP, SpO2 values were recorded after 5, 10, 20, 30, 60, 80 min from the blockade and 10, 30 min, 1, 2, 4, 6, 12 hours after the end of the surgery. Sensory blockade of each nerve was assessed by pinprick test. Sensory blockade was rated by the patient on a verbal analog scale from 100 (normal sensation) to 0 (no sensation). Motor block was evaluated by thumb adduction (ulnar nerve), thumb abduction (radial nerve), flexion of the elbow and pronation of forearm (musculocutaneous), and thumb opposition (median nerve). Motor block evaluation were performed using a modification of the Levvott rating scale from 6 (normal muscular force) to 0 (complete paralysis).

The onset time of the sensory and motor blockades was defined as the time between the end of the local anesthetic injection and no response to the pinprick test and complete paralysis. The duration of sensory block was considered as the time interval between the complete sensory block and the first postoperative pain, and the duration of motor block was defined as the time interval between the complete paralysis and complete recovery of motor function. Time to first analgesic use and total need for analgesics were recorded during postoperative first 12 hours. Postoperative pain levels were evaluated by a 10 cm visual analog scale (VAS) from 0 (no pain) to 10 (severe pain). Hypotension (a 20% decrease from the baseline value), bradycardia (HR < 50 beats per minute), hypoxemia (SpO2 < 90%), nausea and vomiting occurrences were also recorded. If there were hypotension, bradycardia and hypoxemia, it was planned to administrate ephedrine 10 mg IV, atropine 1mg IV and 4-5 l h-1 O2 inhalation therapy respectively. If VAS values were above 4 the patient was given intramuscular (IM) diclofenac 75 mg. The anesthesiologist who evaluated the blockade responses and the patients were blinded as to the solution used.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
1. Sensory and motor block onset time, defined as the time between the end of the local anesthetic injection and no response to the pinprick test and complete paralysis
2. Sensory and motor block durations. The duration of sensory block was considered as the time interval between the complete sensory block and the first postoperative pain, and the duration of motor block was defined as the time interval between the complete paralysis and complete recovery of motor function
3. Time to first analgesic use recorded during postoperative first 12 hours

Secondary outcome measures
1. Mean arterial pressure
2. Heart rate

Overall study start date
20/11/2011

Completion date

28/02/2012

Eligibility

Key inclusion criteria
1. Aged 18-60
2. Male and female participants
3. Scheduled forearm and hand surgery patients

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
64

Total final enrolment
64

Key exclusion criteria
1. Patients with a history of cardiac, respiratory, hepatic, or renal failure, coagulopathy, and allergy to amid local anesthetics
2. Receiving adrenoreceptor agonist or antagonist therapy, chronic analgesic therapy
3. Pregnant women

Date of first enrolment
20/11/2011

Date of final enrolment
28/02/2012

Locations

Countries of recruitment
Türkiye

Study participating centre

Cumhuriyet University
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Sponsor type
University/education

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ROR
https://ror.org/04f81fm77

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Turkey)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2012	17/12/2020	Yes	No