

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison characteristics of Supraclavicular block with bupivacaine 0.5% plus dexmedetomidine and granisetron and Magnesium sulphate in upper extremity orthopedic surgeries

Protocol summary

Study aim

Comparison characteristics of Supraclavicular block with bupivacaine 0.5% plus dexmedetomidine and granisetron and Magnesium sulphate in upper extremity orthopedic surgeries

Design

This study is clinical trial and double blind. The sample size is 105 people. Patients will be divided in 3 groups by simple randomization. Groups are parallel. Trial phase is 3.

Settings and conduct

Patients candidate for upper limb orthopedic surgery in Valiasr hospital in Arak will enter this study. This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Both of gender, 20 to 70 years, ASA class I and II, candidate for orthopedic surgery of upper limb, body mass index lower than 35 Exclusion criteria: Existence of more than one fracture in the body or surgery, coagulation diseases and abnormalities in PTT, PT and INR, psychological problems, pregnancy, neurological disorders in hand

Intervention groups

First group(Dexmedetomidine):We will inject 25 milliliter Bupivacaine 0.5% plus 1 micro gram in kilogram Dexmedetomidine. Second group(magnesium sulfate):We will inject 25 milliliter Bupivacaine 0.5% plus 100 milligram of diluted magnesium sulfate with 2 milliliter of normal saline. Third group(Granisetron): We will inject 25 milliliter Bupivacaine 0.5% plus 3 milligram(3milliliter)Granisetron.

Main outcome variables

Sensory block duration, motor block duration, mean drug use, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N125**

Registration date: **2019-12-13, 1398/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-13, 1398/09/22**

Update count: **0**

Registration date

2019-12-13, 1398/09/22

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison characteristics of Supraclavicular block with bupivacaine 0.5% plus dexmedetomidine and granisetron and Magnesium sulphate in upper extremity orthopedic surgeries

Public title
Comparison characteristics of Supraclavicular block with bupivacaine 0.5% plus dexmedetomidine and granisetron and Magnesium sulphate in upper extremity orthopedic surgeries

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Both of gender 20 to 70 years ASA class I and II
Candidate for orthopedic surgery of upper limb Body mass index lower than 35
Exclusion criteria:
There is more than one body fracture or surgery
Coagulation diseases and disorders in PT,PTT, INR
Psychological problems Pregnancy Neurological disorders in the hand

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with randomization with envelopes in three groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Researcher who complete questionnaire and analyzer and participant are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B and C are available to analyzer and outcome assessor. The drugs in each group are prepared by the anesthesiologist. They are covered with letters A, B and C. Block is performed

by a specialist assistant who is unaware of the medication and interns complete the questionnaires. Internet are also unaware of grouping.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Arak University Of Medical Sciences
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941

Approval date
2019-09-22, 1398/06/31

Ethics committee reference number
IR.ARAKMU.REC.1398.180

Health conditions studied

1

Description of health condition studied
Upper extremity fractures
ICD-10 code
S52.9
ICD-10 code description
Unspecified fracture of forearm

Primary outcomes

1

Description
Duration of motor block
Timepoint
Every 5 minute
Method of measurement
Physical examination

2

Description
Duration of Sensory block
Timepoint

Every 1 minute
Method of measurement
Physical examination

3

Description

Pain

Timepoint

Recovery and 2 and 4 and 8 and 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: We will inject 25 milliliter Bupivacaine 0.5% plus 1 micro gram in kilogram Dexmedetomidine.

Category

Treatment - Drugs

2

Description

Intervention group 2: We will inject 25 milliliter Bupivacaine 0.5% plus 100 milligram of diluted magnesium sulfate with 2 milliliter of normal saline.

Category

Treatment - Drugs

3

Description

Intervention group 3: We will inject 25 milliliter Bupivacaine 0.5% plus 3 milligram(3 milliliter)Granisetron.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Hesamodin Modir

Street address

Valiasr hospital, Valiasr squire

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3848176941

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modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Behnam Mahmodie

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Arak University of Medical Sciences

Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Mohseni

Position

Medicine student

Latest degree

A Level or less

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal Data in SPSS file

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Modir

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments