Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of added Sulfate Magnesium and Dexmedetomidine for prolongation of the duration of sensory and motor block in axillary block

Protocol summary

Summary

Aim of this study is comparison added Sulfate Magnesium and Dexmedetomidine to prolongation duration of sensory and motor block in axillary block. This study is clinical trials and double blind.66 patients' candidate surgery in forearm and hand surgery will enter this study. We will divide patients in two groups (Dexmedetomidine and Sulfate Magnesium) randomly. We will inject 0.5 micro grams in kilogram of Dexmedetomidine and Lidocaine 1.5 percent in first group. We will inject 100 milligram of Sulfate Magnesium and Lidocaine 1.5 percent in second group. We will be total volume 30 milliliter in each group. We will record sensory block in every 1 minute by Bromeg scale and motor block in every 5 minute by Bromeg scale. We will record mean arterial blood pressure and heart rate and oxygen saturation every 5 minute in start to end of surgery. We will record amount of narcotic drug in 24 hours after surgery and pain in recovery and 2 hours after surgery by Visual Analog Scale. Inclusion criteria: ASA class I and II; 18 to 60 years; patients candidate forearm and hand surgery with Axillary block; fracture in forearm and hand Exclusion criteria: infection in area of block; failure in block; surgical time more than 120 minutes; requires sedation needed more

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041920258N38**
Registration date: **2017-06-21, 1396/03/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-21, 1396/03/31

Registrant information

Name
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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Arak University of Medical Sciences

Expected recruitment start date

2017-03-01, 1395/12/11

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of added Sulfate Magnesium and Dexmedetomidine for prolongation of the duration of sensory and motor block in axillary block

Public title

Effect of sulfate Magnesium and Dexmedetomidine in duration of sensory and motor block in Axillary block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA class I and II; 18 to 60 years; patients candidate forearm and hand surgery with

Axillary block; fracture in forearm and hand; lack of coagulation disorders; lack of psychological problems; don't pregnant women ;don't history of allergy to drugs; lack of chronic pain syndrome; lack of neurological disorders in hands; body mass index less than 35 Exclusion criteria: more than one fracture in body and more than one surgery; uncooperative patients for block; infection in area of block; failure in block; surgical time more than 120 minutes; sedation needed more than rates in study

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Arak University Of Medical Sciences

Street address
Dr Mohammad Rafiei, Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City
Arak

Postal code
38149578558

Approval date
2017-02-27, 1395/12/09

Ethics committee reference number
IR.ARAKMU.REC.1395.429

Health conditions studied

1

Description of health condition studied
fracture in forearm

ICD-10 code
S52

ICD-10 code description
Fracture of forearm

2

Description of health condition studied
fracture in hand

ICD-10 code
S62

ICD-10 code description
Fracture at wrist and hand level

Primary outcomes

1

Description
Sensory block

Timepoint
every 1 minute

Method of measurement
Bromeg scale

2

Description
Motor block

Timepoint
every 5 minute

Method of measurement
Bromeg scale

3

Description
Heart rate

Timepoint
Every 15 minute to recovery

Method of measurement
count

4

Description
mean arterial pressure

Timepoint
Every 15 minute to recovery

Method of measurement
Mercury sphygmomanometer

5

Description
oxygen saturation

Timepoint
Every 15 minute to recovery

Method of measurement
pulse oximetry

6

Description
Pain
Timepoint
recovery and 4 hours after surgery
Method of measurement
Visual Analogue Scale Questionnaire

7

Description
mean of narcotic
Timepoint
24 hour after surgery
Method of measurement
miligeram

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1:We will inject 0.5 micro gram in kilogram of Dexmedetomidine and Lidocaine 1.5 percent in first group .
Category
Treatment - Drugs

2

Description
Intervention group 2: We will inject 100 milligram of Sulfate Magnesium and Lidocaine 1.5 percent in second group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Mohammad Tavakoli rad
Street address
Valiasr Hospital, square Valiasr, Shahid Shirodi street, Arak
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Rafiee
Street address
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza Kamali
Position
Faculty member, Anesthesiologist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty