

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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

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 squire, 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

Arak

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

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 863222003

Email

alikalaliir@yahoo.com

Web page address

-

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Tavakolirad

Position

Faculty member, Anesthesiologist

Other areas of specialty/work

Street address

Amiralmomenin hospital, Basij square, Sardasht, Arak

City

Arak

Postal code

3814957558

Phone

+98 634173638

Fax

Email

tavakoli@arakmu.ac.ir

Web page address

-

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr seyed yousef Shahtaheri

Position

resident of anesthesiology

Other areas of specialty/work

Street address

Complex Payambar azam, Basij square, Sardasht, Arak

City

Arak

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 863222003

Email

fa.farokhi@gmail.com

Web page address

-

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