

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of intravenous Dexmedetomidine and Clonidine in change of hemodynamic parameter and block quality after spinal anesthesia with Ropivacaine in lower limb orthopedic surgery

Protocol summary

Summary

Aim of this study is to compare of intravenous Dexmedetomidine and Clonidine in change of hemodynamic parameter and block quality after spinal anesthesia with Ropivacaine in lower limb orthopedic surgery. This study clinical trials and double blind. We will enter 120 patients with spinal anesthesia in lower limb orthopedic surgery in Valiasr hospital. We will inject 0.1 Dexmedetomidine micro gram in kilogram in hours in first group and 0.2 Clonidine micro gram in kilogram in hours in second group and 50 milliliter in litter normal salin. We will record blood pressure and heart rate and oxygen saturation percent in duration surgery every 15 minute. We will sensory block every 1 minute with pin prick method and motor block every 5 minute with Bromeg scale. We will record visual analog scale in recovery and 1 and 2 and 4 and 6 and 12 hours after surgery. Patient refusal to perform spinal anesthesia; failure to perform spinal anesthesia; body mass index more than 30; history of the use of beta-blockers and alpha-2 agonists and calcium channel blockers; cardiovascular disease; pregnancy; coagulation disorders; localized infection in the spinal cord ;history of allergy to the drugs of dexmeditoimidine and clonidine and rupivacaine; arrhythmia; psychological problems; peripheral and central neuropathy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092020258N60**

Registration date: **2017-10-28, 1396/08/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-28, 1396/08/06

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Arak University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2020-03-12, 1398/12/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous Dexmedetomidine and Clonidine in change of hemodynamic parameter and block quality after spinal anesthesia with Ropivacaine in lower limb orthopedic surgery

Public title

Comparison of intravenous Dexmedetomidine and

Clonidine in change of hemodynamic parameter and block quality after spinal anesthesia with Ropivacaine in lower limb orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18 to 60 years; ASA class I and II; both male and female; patients with lower limb orthopedic surgery Exclusion criteria: Patient refusal to perform spinal anesthesia; failure to perform spinal anesthesia; body mass index more than 30; history of the use of beta-blockers and alpha-2 agonists and calcium channel blockers; cardiovascular disease; pregnancy ; coagulation disorders; localized infection in the spinal cord ;history of allergy to the drugs of dexmedetomidine and clonidine and ropivacaine; arrhythmia; psychological problems; peripheral and central homeopathy

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Postal code

38149578558

Approval date

2017-03-12, 1395/12/22

Ethics committee reference number

IR.ARAKMU.REC.1395.450

Health conditions studied

1

Description of health condition studied

Spinal

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

Primary outcomes

1

Description

Blood pressure

Timepoint

Every 15 minute to end of surgery

Method of measurement

Barometer

2

Description

Heart rate

Timepoint

Every 5 minute to end of surgery

Method of measurement

Count

3

Description

Oxygen saturation

Timepoint

Every 15 minute to end of surgery

Method of measurement

Percent

4

Description

Sensory block

Timepoint

Every 1 minute

Method of measurement

Pin prick method

5

Description

Motor block

Timepoint

Every 5 minute

Method of measurement

Bromeg scale

6

Description

Pain

Timepoint

In recovery and 1 and 2 and 4 and 6 and 12 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 2: We will inject Clonidine 0/2 micro gram in kilogram in hours.

Category

Treatment - Drugs

2

Description

Control group: We will inject 50 millimeter in litter normal salin.

Category

Treatment - Drugs

3

Description

intervention group 1: We will inject Dexmedetomidine 0/1 micro gram in kilogram in hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Alireza Sosanabadi

Street address

Valiasr Hospital, 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 Anoshirvani

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Vice chancellor for Research, 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

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 Hesamodin Modir

Position

Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Maryam Javahertalab
Position
Resident of anesthesiology
Other areas of specialty/work
Street address
Payambar Azam Complex, Basij Square, Sardasht,
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City

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