

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of different intrathecal doses of Dexmedetomidine in terms of hemodynamic parameters and block quality after spinal anesthesia with Ropivacaine in lower limb orthopedic surgery

Protocol summary

2017-07-29, 1396/05/07

Summary

The purpose of this study is to compare different intrathecal doses of Dexmedetomidine in terms of hemodynamic parameters and block quality after spinal anesthesia with Ropivacaine in lower limb orthopedic surgery. Design and setting: blocked randomized, double-blind, placebo-controlled trial, single-center, clinical trial phase 2, 81 samples. Inclusion criteria: Candidate for lower limb orthopedic surgery under spinal anesthesia; Age between 18 to 60 years old; ASA class I and II. Exclusion criteria: Use of beta blockers, alpha-2 agonist and calcium channel blockers; Cardiovascular disease; Pregnancy; Coagulopathy; Local infection in the patient's caudal region; Allergy to dexmedetomidine or ropivacaine; History of psychiatric disorders; central or peripheral neuropathy. Interventions: The first group will receive 15 mg ropivacaine and 5 µg dexmedetomidine at a volume of 2 ml intrathecally. The second group will receive 15 mg ropivacaine and 10 µg dexmedetomidine at a volume of 2 ml intrathecally and the third group will receive 15 mg ropivacaine and distilled water at a volume of 2 ml intrathecally. primary outcome: mean arterial pressure; heart rate and pain severity at 1, 2, 4, 6 and 12 hours after end of operation and admission to recovery room.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070614056N12**
Registration date: **2017-07-29, 1396/05/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Hesameddin Modir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 9680

Email address

he_modir@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of different intrathecal doses of Dexmedetomidine in terms of hemodynamic parameters and block quality after spinal anesthesia with Ropivacaine in lower limb orthopedic surgery

Public title

Comparison of different doses of dexmedetomidine in lower limb orthopedic surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Candidate for lower limb orthopedic surgery under spinal anesthesia; Age between 18 to 60 years old; ASA class I and II. Exclusion criteria: Use of beta blockers, alpha-2 agonist and calcium channel blockers; Cardiovascular disease; Pregnancy; Coagulopathy; Local infection in the patient's caudal region; Allergy to dexmedetomidine or ropivacaine; History of psychiatric disorders; central or peripheral neuropathy

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **81**

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

Ethical Committee of Arak University of Medical Sciences

Street address

Arak University Of Medical Science, Basij Square

City

Arak

Postal code

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.ARAKMU.REC.1396.37

Health conditions studied

1

Description of health condition studied

Postoperative pain

ICD-10 code

R52.0

ICD-10 code description

acute pain

Primary outcomes

1

Description

Postoperative pain

Timepoint

at 1, 2, 4, 6 and 12 hours after admission to recovery

Method of measurement

Visual analogue scale

2

Description

Mean arterial pressure

Timepoint

Every 15 min until the end of surgery

Method of measurement

sphygmomanometer

3

Description

Heart rate

Timepoint

Every 15 min until the end of surgery

Method of measurement

Cardiac monitoring

Secondary outcomes

empty

Intervention groups

1

Description

The first group will receive 15 mg ropivacaine and 5 µg dexmedetomidine at a volume of 2 ml intrathecally.

Category

Treatment - Drugs

2

Description

The second group will receive 15 mg ropivacaine and 10 µg dexmedetomidine at a volume of 2 ml intrathecally.

Category

Treatment - Drugs

3

Description

The third or control group will receive 15 mg ropivacaine and distilled water at a volume of 2 ml intrathecally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-Asr Hospital

Full name of responsible person

Dr Hesameddin Modir

Street address

Vali-Asr Hospital, Pirouzi Ave

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences,Vice chancellor
for research

Full name of responsible person

Dr ali arash anoushirvani

Street address

Arak University Of Medical Science, Basij Square

City

Arak

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,Vice chancellor for
research

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 Hesameddin Modir

Position

Anesthesiologist

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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