Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the sedation and analgesia effect of intrathecal dexmedetomidine, fentanyl and neostigmine in femur fracture repair surgery

Protocol summary

Study aim

Comparison of the sedation and analgesia effect of intrathecal dexmedetomidine, fentanyl and neostigmine in femur fracture repair surgery

Design

The present study is a double-blind, parallel-group, randomized clinical trial (using block randomization) on 135 patients.

Settings and conduct

In this double-blind randomized clinical trial, patients who are candidates for hip fracture repair surgery and referred to Valiasr Hospital in Arak will be divided into three equal treatment groups of dexmedetomidine, fentanyl, and neostigmine by block randomization. In this study, patients will be blinded to anesthesia and outcome assessor (by patient coding). Finally, the three groups will be evaluated for study outcomes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidates for surgery to repair a femur fracture and refer to Vali Asr Hospital in Arak; Consent to participate in the study; BMI less than 30; ASA class 1 and 2. Exclusion criteria: Presence of kidney, liver, heart disease and cardiac arrhythmias; Sensitivity to the drugs used; Psychological problems and absence of peripheral and central neuropathy; Local infection in the spinal area.

Intervention groups

Dexmedetomidine group: Patients received 5 micrograms of dexmedetomidine (in a volume of 1 ml) with 15 mg of ropivacaine (3 ml of ropivacaine 0.5%) intrathecally. Fentanyl group: Patients received 50 micrograms of fentanyl (1 ml) with 15 mg of ropivacaine (3 ml of ropivacaine 0.5%) intrathecally. Neostigmine group: Patients received 50 mg of neostigmine (in a volume of 1 ml) with 15 mg of ropivacaine (3 ml of ropivacaine 0.5%) intrathecally.

Main outcome variables

Onset of sensory and motor block, pain score, mean arterial pressure, heart rate, arterial oxygen saturation, duration of sensory and motor block, postoperative complications, mean narcotics consumed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N33**
Registration date: **2025-04-04, 1404/01/15**
Registration timing: **prospective**

Last update: **2025-04-04, 1404/01/15**
Update count: **0**

Registration date

2025-04-04, 1404/01/15

Registrant information

Name

Amin Haji seyyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3366 7583

Email address

amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-09, 1404/01/20

Expected recruitment end date

2025-07-11, 1404/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the sedation and analgesia effect of intrathecal dexmedetomidine, fentanyl and neostigmine in femur fracture repair surgery

Public title

Sedation and analgesia of dexmedetomidine, fentanyl, and intrathecal neostigmine in femoral surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for femur fracture repair surgery and refer to Vali Asr Hospital in Arak Consent to participate in the study BMI less than 30 ASA Class One and Two

Exclusion criteria:

Presence of kidney, liver, heart disease, and cardiac arrhythmias Allergy to the medications used Psychological problems and absence of peripheral and central neuropathy Local infection in the spinal area

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to three intervention groups in order of arrival and based on a randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. A block randomization method with blocks of 9 will be used to allocate samples. Thus, using the site www.sealedenvelope.com, blocks of 9 letters A, B, and C will be randomly generated based on the sample size. The order of the letters A, B, and C in each block from the first block to the last block is considered as the randomization sequence. The generation of these blocks and their random sequence is entirely done by this site and the researcher is not aware of their sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be based on a double-blind design. In this way, the anesthesiologist performing spinal anesthesia is aware of the patient grouping, but the patients and the intern who is responsible for collecting the data are unaware of the groupings, and finally the relevant intern will record the clinical information and outcomes of each patient and deliver it to the statistician. Patients who are anesthetized and are not aware of the medication they receive. Therefore, in this study, it can be stated that the patients and the intern evaluating the data are unaware of the groupings.

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 Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2024-09-08, 1403/06/18

Ethics committee reference number

IR.ARAKMU.REC.1403.199

Health conditions studied

1

Description of health condition studied

Femur fracture repair surgery

ICD-10 code

M80.05

ICD-10 code description

Age-related osteoporosis with current pathological fracture, femur

Primary outcomes

1

Description

Pain score

Timepoint

Postoperatively, during recovery and 2, 4, 6, 12, and 24 hours after surgery

Method of measurement

visual analog scale

2

Description
Onset of sensory and motor block
Timepoint
After spinal anesthesia
Method of measurement
Minute

3

Description
Duration of sensory and motor block
Timepoint
It is measured from the start of spinal anesthesia to its end.
Method of measurement
Minute

Secondary outcomes

empty

Intervention groups

1

Description
Dexmedetomidine group: Patients receive 5 micrograms of dexmedetomidine (in a volume of 1 ml) manufactured by Exir Company of Iran along with 15 mg of ropivacaine (3 ml of ropivacaine 0.5%) manufactured by Molteni Company of Italy intrathecally.
Category
Treatment - Drugs

2

Description
Fentanyl group: 50 micrograms of fentanyl (1 ml) (manufactured by Caspian Tamin Company - Rasht, Iran) along with 15 mg of ropivacaine (3 ml of ropivacaine 0.5%) manufactured by Molteni Company, Italy, were administered intrathecally.
Category
Treatment - Drugs

3

Description
Neostigmine group: 50 mg of neostigmine (in a volume of 1 ml) manufactured by Caspian Tamin Pharmaceutical Company, Rasht – Iran, along with 15 mg of ropivacaine (3 ml of ropivacaine 0.5%) manufactured by Molteni Company, Italy, were administered intrathecally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Valiasr Hospital
Full name of responsible person
Dr. Hesamuddin Modir
Street address
Vali Asr hospital, Shahid Shiroudi Street, Arak, Iran
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3814957558
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modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Street address
Vali Asr hospital, Shahid Shiroudi Street, Arak, Iran
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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. Hesamuddin Modir

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Dr. Alireza Amani

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Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long
Access will be from 2025/06/20 to 2028/06/20 for 3 years.

To whom data/document is available
University researchers

Under which criteria data/document could be used
Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable
University researchers and university professors can request Dr. Ahmadreza Behrouzi to use the data after contacting the relevant professor via message or email. Dr. Hesamuddin Modiri: Phone: 09183615107 Email:

modir.he@gmail.com, Address: Valiasr Hospital, Arak, Vice-Chancellor of Hospital Education

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

Letter writing should be done with professors and universities.

Comments