

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of intrathecal injections of Meperidine, Teramadol, Magnesium sulfate and Dexmedetomidine in prevention of shivering and postoperative complications of femoral fracture repair under spinal anesthesia

Protocol summary

Study aim

Comparison of intrathecal injections of Meperidine, Teramadol, Magnesium sulfate and Dexmedetomidine in prevention of shivering and postoperative complications of femoral fracture repair under spinal anesthesia

Design

The study of the two-course clinical trial of 132 patients was randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Candidates for femoral fracture repair under spinal anesthesia in Valiasr Hospital in Arak are divided into 3 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 75 years old; both sexes; ASA Class 1 and 2; femoral fracture repair under spinal anesthesia; no history of drug addiction; no history of seasonal allergies as well as allergies to any of the drugs used in this study; no history of neuromuscular diseases, Raynaud's disease, cardiomyopathy and coagulation disease. Exclusion criteria: failure in anesthesia and other methods; dissatisfaction with continuing to participate in the project.

Intervention groups

Dexmedetomidine group: They receive 5 micrograms of dexmedetomidine along with 12.5 mg of hyperbaric bupivacaine 0.5% (2.5 ml). Magnesium sulfate group: They receive 25 mg of magnesium sulfate along with 12.5 mg of hyperbaric bupivacaine 0.5% (2.5 ml). Meperdin group: They receive 0.2 mg / kg of meperidine along with 12.5 mg of hyperbaric bupivacaine 0.5% (2.5 ml). Tramadol group: They receive 10 mg of tramadol (0.2 ml of tramadol hydrochloride 50 mg / ml) along with 12.5 mg of hyperbaric bupivacaine 0.5% (2.5 ml).

Main outcome variables

Shivering intensity; sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N153**

Registration date: **2021-03-09, 1399/12/19**

Registration timing: **prospective**

Last update: **2021-03-09, 1399/12/19**

Update count: **0**

Registration date

2021-03-09, 1399/12/19

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-15, 1399/12/25

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intrathecal injections of Meperidine, Teramadol, Magnesium sulfate and Dexmedetomidine in prevention of shivering and postoperative complications of femoral fracture repair under spinal anesthesia

Public title

Comparison of intrathecal injections of Meperidine, Teramadol, Magnesium sulfate and Dexmedetomidine in prevention of shivering and postoperative complications of femoral fracture repair under spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 18 to 75 years old Both sexes ASA Class 1 and 2
Femoral fracture repair under spinal anesthesia No history of drug addiction No history of seasonal allergies as well as allergies to any of the drugs used in this study
Absence of neuromuscular diseases Absence of Raynaud's disease Absence of cardiomyopathy Absence of coagulation disease

Exclusion criteria:

Failure in anesthesia and other methods Dissatisfaction with continuing to participate in the project

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random allocation with envelopes in 4 groups A and B and C and D. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcome assessor and data analyzer and participant are

blind (double blind). Outcome assessor and data analyzer and participant don't aware from grouping.

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

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-01-13, 1399/10/24

Ethics committee reference number

IR.ARAKMU.REC.1399.297

Health conditions studied**1****Description of health condition studied**

Femoral fracture repair under spinal anesthesia

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

Primary outcomes**1****Description**

Shivering intensity

Timepoint

In recovery and every 15 minutes to 2 hours and then every 2 hours to 12 hours

Method of measurement

Fourth criterion (0-3): 0 means no shivering, 1 means mild fasciculation of the face and neck, 2 means visible tremor in more than one muscle, and 3 means intense muscle activity throughout the body.

2**Description**

Sedation

Timepoint

During the operation and up to 12 hours after the operation

Method of measurement

Ramsay Sedation Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: They receive 5 micrograms of dexmedetomidine along with 12.5 mg of hyperbaric bupivacaine 0.5% (2.5 ml). (Dexmedetomidine Elixir Pharmaceutical Company - Iran)

Category

Treatment - Drugs

2**Description**

Intervention group: They receive 25 mg of magnesium sulfate along with 5.12 mg of hyperbaric bupivacaine 0.5% (2.5 ml). (Magnesium sulfate 10% Pasteur Institute Pharmaceutical Company - Iran)

Category

Treatment - Drugs

3**Description**

Intervention group: They receive 0.2 mg / kg of meperidine along with 12.5 mg of hyperbaric bupivacaine 0.5% (2.5 ml). Meperidine Gerot Pharmaceutical Company Vienna - Austria (Order of Darupakhsh Company)

Category

Treatment - Drugs

4**Description**

Intervention group: They receive 10 mg of tramadol (0.2 ml of tramadol hydrochloride 50 mg / ml) along with 12.5 mg of hyperbaric bupivacaine 0.5% (2.5 ml). (Travadol Caspian Tamin Rasht Pharmaceutical Company - Iran)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Hesamodin Modir

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Valiasr hospital, Valiasr square, Shahid Shirodi street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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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 Esmaeel Moshiri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Dr Hesamedin Modir

Position

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Latest degree

Specialist

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Person responsible for updating data

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Full name of responsible person

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medicine student

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A Level or less

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available