

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effect of intravenous injection of meperidin with dexamethasone and midazolam on postoperative shivering in patients recovering from general anaesthesia in post orthopedic surgery

Protocol summary

Study aim

Comparison of the effect of intravenous injection of meperidin with dexamethasone and midazolam on postoperative shivering in patients recovering from general anaesthesia in post orthopedic surgery

Design

Three arm parallel group randomized trial with 40 patients in each group, randomized with block randomization method. Block randomization method is used for allocation.

Settings and conduct

This study will be performed in Madani hospital, Karj on all participants with orthopedic surgeries under general anaesthesia eligible for the study. Patients who have consciously signed a consent form to participate in the project will be randomly assigned to three groups. The randomization list will be prepared by the statistician. Treatments will be placed in sealed envelopes and will be kept by the out-of-study nurse. After identification of the eligibility of the patient, the procedure will be explained to her and informed consent will be obtained, completing the final information is the responsibility of the person who is unaware of the type of treatment. The statistician will also be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing elective orthopedic surgery, at least 8 hours of fasting, ages between 18 and 65 years, ASA class 1,2. Exclusion criteria: Having hypothermia or hyperthermia.

Intervention groups

Intervention group 1: participants will receive meperidine at a dose of 0.4 mg per kg. Group 2: participants will receive dexamethasone at a dose of 0.15 mg per kg. Intervention group 3: participants will receive midazolam at a dose of 0.05 mg per kg.

Main outcome variables

Shivering after surgery with general anaesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211226053537N1**

Registration date: **2022-01-23, 1400/11/03**

Registration timing: **prospective**

Last update: **2022-01-23, 1400/11/03**

Update count: **0**

Registration date

2022-01-23, 1400/11/03

Registrant information

Name

maryam cheraghali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2275 2546

Email address

cheraghalmariyam@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-05-05, 1401/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intravenous injection of meperidin with dexamethasone and midazolam on postoperative shivering in patients recovering from general anaesthesia in post orthopedic surgery

Public title

Comparison of the effect of intravenous meperidine injection with dexamethasone and midazolam on shivering after orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing elective orthopedic surgery At least 8 hours of fasting Ages between 18 and 65 years ASA class 1,2

Exclusion criteria:

hypothermia hyperthermia

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 120 people, with 40 people in each group. Block randomization method was designed by epidemiologist using STATA version 13 software. The number of blocks considered is 6

Blinding (investigator's opinion)

Triple blinded

Blinding description

The random allocation list will solely available to the epidemiologist. 120 cards containing sequences of treatments will be written and be placed inside sealed envelopes. A 10-digit random code, as the patient's identification number, will be provided for each packet. When the physician announces the eligibility of a patient, the nurse will provide the physician with the envelope. None of the patients should be aware of the type and process of treatment. Also, the person evaluating the outcomes is a third person who is unaware of the random allocation process and type of treatment. Data analysis will be carried out by a statistician who is aware of all the processes performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Ethics committee unit; Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2022-01-04, 1400/10/14

Ethics committee reference number

IR.ABZUMS.REC.1400.259

Health conditions studied

1

Description of health condition studied

Shivering after surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

shivering after general anesthesia

Timepoint

In the meperidine group and the midazolam group; 2 minutes and in the dexamethasone group 5 minutes after injection.

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: participants will received meperidine (Exire, Iran) at a dose of 0.4 mg per kg

Category

Treatment - Drugs

2

Description

Intervention group2: participants will received dexamethasone (Alborz daro,Iran) at a dose of 0.15 mg per kg

Category

Treatment - Drugs

3

Description

Intervention group3: participants will received midazolam(shimi daro,Iran) at a dose of 0.05 mg per kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani hospital

Full name of responsible person

Maryam Cheraghali

Street address

Karaj, Madani Square, Madani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Nourisepehr

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Research@abzums.ac.ir

Grant name

Karaj University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Maryam Cheraghali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Latest degree

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Position

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Latest degree

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Other areas of specialty/work

Anesthesiology

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Province

Alborz

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