Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of intravenous injection of meperidin with dexamethasone and midazolam onpostoperative 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 onpostoperative 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 anesthesia 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 received meperidine at a dose of 0.4 mg per kg. Goup2: participants will received dexamethasone at a dose of 0.15 mg per kg Intervention group3: participants will received midazolam at a dose of 0.05 mg per kg

Main outcome variables

Shivering after surgery with general anesthesia

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

cheraghalimaryam@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 onpostoperative 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 120people, 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. A10-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
Street address
Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street
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Phone
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Email
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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Person responsible for updating data

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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