Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of prophylactic use of meperidine, meperidine plus dexamethasone, and ketamin plus midazolam for preventing of shivering during spinal anesthesia:A Randomized, Double blind, Placebo-Controlled study.

Protocol summary

Summary

In this prospective, double blind, placebo controlled study 200 ASA I and II patients undergoing orthopedic or urologic surgery under spinal anesthesia are included.Subarachnoid anesthesia is performed by using 15 mg of 0.5%hyperbaric bupivacaine.Patients are randomly allocated to receive saline(placebo,Group C), meperidine 0.4 mg/kg(Group M), ketamine 0.25 mg/kg plus midazolam 37.5 µg/kg(Group KM), and meperidine0.2 mg/kg plus dexamethasone 0.1 mg/kg(Group MD).All drugs are given as an intravenous (i.v) bolus immediately after intrathecal injection.During surgery and stay in the recovery room shivering score, blood pressure and some other adverse effects are recorded at 5 minutes interval.Axillary and tympanic temperature are recorded at 15 min intervals during the perioperative period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120220185N1**
Registration date: **2015-01-10, 1393/10/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-10, 1393/10/20

Registrant information

Name

ALI SOLHPOUR

Name of organization / entity

SHAHID BEHESHTI MEDICAL UNIVERSITY

Country

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-01-09, 1393/10/19

Expected recruitment end date

2015-02-09, 1393/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of prophylactic use of meperidine, meperidine plus dexamethasone, and ketamin plus midazolam for preventing of shivering during spinal anesthesia:A Randomized, Double blind, Placebo-Controlled study.

Public title

The effect of combination of dexamethasone and meperidine intravenously in prevention of post-spinal anesthesia.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:patients with elective orthopedic or

urologic surgery aged between 20 and 60 years old. Exclusion criteria: Patients with cardiopulmonary disease; hypothyroidism or hperthyroidism; patients with psychologic disorders, a need for transfusion during surgery; an initial body temperature more than 38 or less than 36◦ C; a known history of alcohol or substance abuse; or receiving vasodilators; or medications likely to alter thermoregulation; patients with spinal anesthesia failure.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **200**

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
Shahid Beheshti Medical University

Street address
Chamran highway, Yaman street, Arabi street, Shahid Beheshti Medical University

City
Tehran

Postal code

Approval date
2013-12-01, 1392/09/10

Ethics committee reference number
SBMU.rec.1392.485

Health conditions studied

1

Description of health condition studied
Spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Shivering score

Timepoint
Thirty minutes after spinal anesthesia

Method of measurement
Observation based on Tsai scale

Secondary outcomes

1

Description
Surface and core temperature

Timepoint
Every 15 minutes

Method of measurement
Based on centigrade,Ear termometer for core temperature and axillary termometer for surface temperature

Intervention groups

1

Description
Meperidine 0.4 mg/kg, intravenously bolus immediately after intrathecal injection

Category
Prevention

2

Description
Ketamine 0.25 mg/kg plus midazolam 37.5 µg/kg, intravenously bolus immediately after intrathecal injection

Category
Prevention

3

Description
Meperidine 0.2 mg/kg plus dexamethasone 0.1 mg/kg, intravenously bolus immediately after intrathecal injection

Category
Prevention

4

Description
Normal saline 5 cc, intravenously immediately after intrathecal injection as placebo

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ali Solhpour
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Department of Anesthesiology, Labafinejad hospital, 9th Boostan, Pasdaran street
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Sponsors / Funding sources

1

Sponsor
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Ali Solhpour, Alireza Jafari
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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
Shahid Beheshti Medical University
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
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Person responsible for updating data

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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