

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 meperidine 0.2 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

Iran (Islamic Republic of)

Phone

+98 21 2254 3731

Email address

solhpourali@sbmu.ac.ir

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 hyperthyroidism; patients with psychological 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 thermometer for core temperature and axillary thermometer 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

Street address

Department of Anesthesiology, Labafinejad hospital,
9th Boostan, Pasdaran street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti Medical University

Full name of responsible person

Ali Solhpour, Alireza Jafari

Street address

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

City

Tehran

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

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Solhpour

Position

Medical Doctor, Anesthesiologist

Other areas of specialty/work

Street address

Department of Anesthesiology, Labafinejad hospital,
9th Boostan, Pasdaran street

City

Tehran

Postal code

Phone

+98 21 2254 3731

Fax

Email

solhpourali@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Solhpour

Position

Medical Doctor, Anesthesiologist

Other areas of specialty/work

Street address

Department of anesthesiology, Labafinejad hospital,
9th Boostan, Pasdaran street

City

Tehran

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+98 21 2254 3731

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solhpourali@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Web page address

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