

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of Preemptive Clonidine versus Pethidine and Ketamine on Postoperative Shivering in addicted patients during Spinal Anesthesia in elective orthopedic surgery

Protocol summary

Summary

The aim of the study is to compare the effect of preemptive clonidine, ketamin and pethidine in controlling postoperative shivering in addicted patients who undergo spinal anesthesia. In a clinical trial, 81 patients candidate for elective orthopaedic surgery for lower limb are enrolled and randomly assigned to groups of 27 members. Randomization is performed using random numbers generated by the computer. Exclusion criteria are massive blood transfusion; psychiatric disorders; hypothermia ($t < 36$) or hyperthermia ($t > 38$). Clonidine 0.2 mg is administered orally prior to surgery. Ketamin 2mg/kg and pethidine 0.5 mg/kg are administered through surgery to the patients. Postoperative shivering will be measured in patients during staying in post anesthesia care unit. Blood pressure and heart rate will be recorded during 30 minutes after spinal anesthesia in operating room.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042333615N1**
Registration date: **2017-06-30, 1396/04/09**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-30, 1396/04/09

Registrant information

Name

Mahshid Ghasemi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Anesthesiology Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Preemptive Clonidine versus Pethidine and Ketamine on Postoperative Shivering in addicted patients during Spinal Anesthesia in elective orthopedic surgery

Public title

Control of shivering after surgery in addicted patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA class I to II; age between 20 to 60 years; BMI less than 30 kg/m²; scheduled for elective lower extremity surgery. Exclusion criteria: History of hyper or hypothyroidism; Parkinson's disease; massive blood transfusion; psychiatric disorders; hypothermia < 36 or hyperthermia > 38; alcoholism; tremor

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization was done using computer generated numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak st, Tehran, Iran

City

Tehran

Postal code

15683287

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

C/1392/1146

Health conditions studied

1

Description of health condition studied

Post operative shivering

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post-operative shivering

Timepoint

0,5,10,15,20 minutes in recovery room

Method of measurement

Asking and observing patient

Secondary outcomes

1

Description

systolic and diastolic blood pressure

Timepoint

0.5, 10, 15 and 20 minutes after surgery in recovery room

Method of measurement

monitoring

2

Description

Postoperation pulse oxymetry

Timepoint

0.5, 10, 15 and 20 minutes after surgery in recovery room

Method of measurement

monitoring

3

Description

heart rate

Timepoint

0.5, 10, 15 and 20 minutes after surgery in recovery room

Method of measurement

monitoring

Intervention groups

1

Description

Intervention group A: Ketamin 2mg/kg is administered during surgery to the patients.

Category

Treatment - Drugs

2

Description

Intervention group B: Pethidine 0.5 mg/kg is administered during surgery to the patients

Category

Treatment - Drugs

3

Description

Intervention group C: Clonidine 0.2 mg is administered orally prior to surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Dr. Mahshid Ghasemi

Street address

no.20 , Velenjak St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaee

Street address

Velenjak St

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Shahid Beheshti
University of Medical Sciences

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

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assistant professore

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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