Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Preemptive Clonidnine 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 anethesia care unit. Blood pressure and heart rate will be recorded during 30 minutes after spinal anethesia 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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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 Clonidnine 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 oxymetery
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
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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