

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

+98 21 2226 5454

##### Email address

mahshidghasemi@sbmu.ac.ir

##### 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/m<sup>2</sup>; 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

**City**

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**

Dr. Mahshid Ghasemi

**Position**

assistant professore

**Other areas of specialty/work**

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**Web page address**

## Person responsible for scientific inquiries

#### Contact

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Dr.Mahshid Ghasemi

**Position**

Assistant Professor

**Other areas of specialty/work**

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## Person responsible for updating data

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**Other areas of specialty/work**

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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*