# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## A comparison of efficacy of intravenous ketamine and tramadol in preventing post-operative shivering in general anesthetic patients

## Protocol summary

**Summary**

The aims of this study it to determine the efficacy of ketamine and tramadol in preventig post_operative shivering. This study will be done as a double-blind randomized controlled clinical trial. Inclusion and exclusion criteria: 1) Age range of 18-65 2) BMI<30 3)No history of seizur or multiple allergia 4)No history of cardiovascular diseases HTN Exclusion: 1)Any patient need blood or blood supply transfusionduring surgery 2)Body temperature below 35 durin the surgery Each patient will be given a code according to the place where he or she stands in our list and depending on the given code, they will enter in one of the control (S: normal salin) or ketamine (K) or tramadol (T) groups (Total=150). We will inject 2 cc normal salin to group S, 0.5 mg/kg ketamin to group K and 0.3 mg/kg tramadol to groupe T 0.5 hour before finishing the surgery. Post-operative shivering will be evaluated by crosly scale and post-operative pain will be evaluated by VAS score.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201011164819N2**
Registration date: **2011-07-27, 1390/05/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2011-07-27, 1390/05/05

**Registrant information**

**Name**

Saied Morteza Heidari Tabaei Zavareh

**Name of organization / entity**

Isfahan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Isfahan University of Medical Sciences

**Expected recruitment start date**

2011-04-21, 1390/02/01

**Expected recruitment end date**

2011-07-23, 1390/05/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparison of efficacy of intravenous ketamine and tramadol in preventing post-operative shivering in general anesthetic patients

**Public title**

Comparison of efficacy of ketamine and tramadol in preventing post-operative shivering

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Aged between 18 and 65; BMI less than 30; No history of seizur or multiple allergia; No history of cardiovascular diseases HTN Exclusion criteria: needs to blood or blood supply transfusion during surgery

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **150**
**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**
Isfahan University of Medical Sciences
**Street address**
Isfahan - Hezarjerib St.
**City**
Isfahan
**Postal code**
**Approval date**
2010-02-24, 1388/12/05
**Ethics committee reference number**
388568

## Health conditions studied

### 1

**Description of health condition studied**
post_operative shivering
**ICD-10 code**
T88.5
**ICD-10 code description**
Other complications of anaesthesia

## Primary outcomes

### 1

**Description**
Tympanic temperatur
**Timepoint**
Before induction of anesthesia - After induction of anesthesia - 30 min. after induction of anesthesia - At the time of entering to recovery - 15 min. after - 30 min. after
**Method of measurement**
With digital tympanic thermometer

### 2

**Description**
Axillary temperature
**Timepoint**
Before induction of anesthesia - After induction of anesthesia - 30 min. after induction of anesthesia - At the time of entering to recovery - 15 min. after - 30 min. after
**Method of measurement**
Mercuric Thermometer

## Secondary outcomes

### 1

**Description**
VAS Score of pain
**Timepoint**
At entering to recovery - 15 min. later - 30 min. later
**Method of measurement**
VAS Score bethween 0-10

### 2

**Description**
VAS Score of nausea
**Timepoint**
In recovery room - During 24 hours later
**Method of measurement**
VAS Score of nausea bethween 0-10

### 3

**Description**
vomiting
**Timepoint**
In recovery room - During 24 hours later
**Method of measurement**
Frequency

### 4

**Description**
Dizziness
**Timepoint**
In recovery room
**Method of measurement**
Observation & asking the patient

### 5

**Description**
Headache
**Timepoint**
In recovery room
**Method of measurement**
Observation & asking the patient

**6**

**Description**
Halucination
**Timepoint**
In recovery room
**Method of measurement**
Observation

**7**

**Description**
Recovery stay time
**Timepoint**
End of recovery stay
**Method of measurement**
Minute

## Intervention groups

**1**

**Description**
In second group, 30 min. before finishing anesthesia we will inject 0.5 mg/kg of ketamine intravenusely
**Category**
Treatment - Drugs

**2**

**Description**
In third group, we will inject 2 cc N/S IV, 30 min. before finishing anesthesia.
**Category**
Placebo

**3**

**Description**
In First group, we will inject 0.3 mg/kg of tramadol IV, 30 min. before finishing anesthesia.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Alzahra hospial
**Full name of responsible person**
Saied Morteza Heidari - Anesthesiologist - assistent professor
**Street address**
Hezar jarib Aven-Isfahan University Of Medical Sciences and Health Services-Isfahan-Iran
**City**
Isfahan

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Isfahan University of Medical Sciences
**Full name of responsible person**
Dr. Saied Morteza Heidari Tabaei Zavareh
**Street address**
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**City**
Isfahan
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Isfahan 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**
Isfahan University of Medical Sciences
**Full name of responsible person**
Dr. Saied Morteza Heidari Tabaei Zavareh
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Assistant Professor - Anesthesiologist
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## Person responsible for scientific inquiries

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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*