

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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)

Phone

+98 31 1267 6415

Email address

m_heidari@med.mui.ac.ir

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 between 0-10

2

Description

VAS Score of nausea

Timepoint

In recovery room - During 24 hours later

Method of measurement

VAS Score of nausea between 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 intravenously

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 - assistant 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

Hezar jarib Aven-Isfahan University Of Medical Sciences and Health Services-Isfahan-Iran

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

Position

Assistant Professor - Anesthesiologist

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr. Saied Morteza Heidari Tabaei Zavareh

Position

Assistant Professor - Anesthesiologist

Other areas of specialty/work**Street address**

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Dr.alinoroozi@gmail.com

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

Person responsible for updating data**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Ali noroozi

Position

M.D

Other areas of specialty/work**Street address**