

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison between ketamine 0.25 mg/kg and ketamine 0.5 mg/kg for relieving postoperative shivering after elective abdominal hysterectomy

Protocol summary

Study aim

Determination the effect of low doses of ketamine on prevention of shivering after abdominal hysterectomy

Design

A randomized, double-blind, placebo controlled clinical trial

Settings and conduct

The site of research is Yas Hospital. After approval by the Ethics and Clinical Studies Committee of Tehran University of Medical Science the investigation will be started. Informed consents will be obtained from all of the patients. All the patients will be anesthetized with standard method. The study drugs are being prepared by a person who is not subsequently involved in the research and will be packed in an envelope that the patient code has been written on it and 20 minutes before the end of operation will be opened and injected. The anesthesiologist of operation room and all operation and recovery room nurses and the nurses responsible for the questionnaire are unaware of the type of drug and the patient group. After awakening, the severity and frequency of shivering and analgesic request will be recorded for up to 4 hours. At the end of the study, the incidence and severity of shivering between the groups will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 35-65, elective abdominal hysterectomy candidate, ASA class 1-2, benign diagnosis
Exclusion criteria: surgery time more than 3 hours; Abnormal hemorrhage or transfusion during surgery, diagnosis of malignancy, symptom of arrhythmia, liver, kidney, psychotic diseases and hypertension
Unwillingness to work with scholars

Intervention groups

group 1 : 0/25 mg/kg ketamin intravenously with 2 cc volume, 20 minutes before the end of surgery
group 2: 0/5 mg/kg ketamin intravenously with 2 cc volume, 20 minutes before the end of surgery
group 3: 2cc normal saline intravenously, 20 minutes before the end of

surgery

Main outcome variables

Incidence and severity of postoperative shivering after TAH

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190409043219N1**
Registration date: **2019-05-25, 1398/03/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-18, 1398/05/27**

Update count: **1**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Saghar Samimi Sadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4216 0000

Email address

sagharsamimi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2019-08-11, 1398/05/20

Trial completion date

2019-08-18, 1398/05/27

Scientific title

Comparison between ketamine 0.25 mg/kg and ketamine 0.5 mg/kg for relieving postoperative shivering after elective abdominal hysterectomy

Public title

effect of ketamine on postoperative shivering

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

female 35-65 yrs ASA class 1-2 benign diagnosis without any symptom of arrhythmia ,liver disease,kidney disease,psychotic disease and hypertension

Exclusion criteria:

surgery time more than 3 hrs abnormal bleeding or need to transfusion through the surgery till 48 hrs after the ending of procedure or taking hypnotic drugs from 72 hrs before the procedure diagnosis of malignancy refuse to cooperate with researchers

Age

From **35 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **96**

Actual sample size reached: **133**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly allocated to 1 of 3 treatment groups using balanced block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

The study medications are prepared by an anesthesiologist who does not otherwise participated in the study and then are enveloped and sealed and patient's code are recorded on it. The envelopes will open in operation room 20 min before the end of surgery by an anesthesiologist who is blinded to patient's study group and type of solution. All of the nurses and patients are blinded to the type of solution and to the patient's study group allocation.also the nurse who fill the questionnaire.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics and Clinical Studies Committee of Tehran University of Medical Sciences

Street address

Yas Hospital, North Ostad Nejatollahi Ave, Karim Khan Zand St.

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2018-01-02, 1396/10/12

Ethics committee reference number

۱۳۹۶.۰۱۲۰.۰۱۲.۰۱۲.۰۱۲.TUMS.MEDICINE.REC.

Health conditions studied**1****Description of health condition studied**

post operative shivering

ICD-10 code

R68.8

ICD-10 code description

Other specified general symptoms and signs

Primary outcomes**1****Description**

incidence and severity of post operative shivering

Timepoint

0-5-10-15-20-60-120, 240 minutes post operative

Method of measurement

the frequency of shivering will be recorded on a questionnaire

2**Description**

severity of shivering will be determined and recorded based on 0-4 scoring system

Timepoint

0-5-10-15-20-60-120, 240 minutes post operative

Method of measurement

the severity of shivering will be recorded on a questionnaire

Secondary outcomes

1

Description

The need to treatment with pethidine

Timepoint

Each time in the first 4 hours after surgery That the patients request a pain killer medication

Method of measurement

Recording the consumption of pethidine in mg in a questionnaire by the nurse

2

Description

Changes in core body temperature during anesthesia.

Timepoint

Just before the anesthesia begins and 30, 60, 90, min after it and also at 0 and 15 min of recovery time.

Method of measurement

Using Walch Allyn Braun Pro 6000 Tympanic thermometer

Intervention groups

1

Description

Intervention group: :injection of 0/25 mg/kg ketamin intravenously with 2 cc volume, 20 minutes before the end of surgery

Category

Prevention

2

Description

Intervention group: injection of 0/5 mg/kg ketamin intravenously with 2 cc volume, 20 minutes before the end of surgery

Category

Prevention

3

Description

Control group: 2cc normal saline intravenously , 20 minutes before the end of surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

Saghar Samimi Sadeh

Street address

Yas Hospital, North Ostad Nejatollahi Ave. Karim Khan Zand Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shirin Niroomanesh

Street address

Yas hospital, North Ostad Nejatollahi Ave, Karim Khan Zand Street

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yashospital@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Saghar Samimi Sadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available