Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of intra-operative magnesium and ketamine combination on pain control after abdominal hysterectomy

Protocol summary

Summary

The aim of this study is evaluation the effect of intraoperative magnesium and ketamine combination on postoperative pain after abdominal hysterectomy. In this randomized double-blind clinical trial, 66 patients, ASA class I and II undergoing abdominal hysterectomy are studied. The study group (n=33) receive bolus dose of magnesium sulfate (50% Magnesium Sulfate 0.5 gm/ml; Pasteur Institute of Iran)1g into 100ml normal saline over 15 min and bolus ketamine (Ketamine HCL 50 mg/ml; TRITTAU; Germany) 15 mg over 2-3 min prior to induction of anesthesia. Then magnesium sulfate 1g with ketamine 30 mg into 300ml normal saline is infused during surgery until the end of operation. In the placebo group same volume of normal saline (NaCl 500 ml; Shahid Ghazi Pharmacuetical; Tabriz; IRAN) is infused at the similar times. Intensity of postoperative pain according to VAS in PACU and at 1,3,6,12 and 24 h after surgery, time of first request to analgesic, overall dose of analgesics, time of ambulation and hospitalization, side effects and magnesium values (before and 24h after surgery) are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608157013N12**
Registration date: **2016-09-04, 1395/06/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-04, 1395/06/14

Registrant information

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Simin Atashkhoei
Name of organization / entity
Tabriz University of Medical Siences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intra-operative magnesium and ketamine combination on pain control after abdominal hysterectomy

Public title

Effect of intraoperative magnesium and ketamine combination on postoperative pain after abdominal hysterectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Scheduled for elective abdominal hysterectomy; ASA class I, II. Exclusion criteria: Emergence hysterectomy; history of systemic diseases

(renal, cardiovascular; respiratory, hepatic, neuromuscular and ...); history of psychopathy; BMI>35; calcium Chanel inhibitor consumption; recent magnesium therapy; history of chronic pain syndrome; pregnancy; history of alcohol and opioid consumption

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Patients were randomly assigned to study group (n = 33), and placebo group (n = 33) using a computer-generated randomization list.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ettics Committee of Tabriz University of Medical Sciences

Street address
Vice chancellor for research, Tabriz University, Daneshgah Street, Tabriz

City
Tabriz

Postal code

Approval date
2016-06-12, 1395/03/23

Ethics committee reference number
IR.TBZMED.REC.1395.222

Health conditions studied

1

Description of health condition studied
Acute postoperative pain

ICD-10 code
R50-R69

ICD-10 code description
R52.0 Acute Pain

Primary outcomes

1

Description
pain

Timepoint
PACU and at 1, 3, 6, 12 and 24h after surgery

Method of measurement
visual analogue scale(VAS) (0= non to 10= severe pain) cm)

Secondary outcomes

1

Description
Overall dose of postoperative analgesic

Timepoint
PACU and during 24h postoperatively

Method of measurement
number and amount of medication by mg

Intervention groups

1

Description
The study group (n=33) receive bolus dose of magnesium sulfate 1g into 100ml normal saline over 15 min and bolus ketamine 15 mg over 2-3 min prior to induction of anesthesia. Then magnesium sulfate 1g with ketamine 30 mg into 300ml normal saline is infused during surgery until the end of operation.

Category
Prevention

2

Description
In the placebo group: normal saline 100ml during 15 min before the surgery and 300 ml during surgery are infused.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Medical education Center

Full name of responsible person
Dr. Simin Atashkhoei

Street address
Al-Zahra Hospital, Sought Artesh Street,Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for reaserch, Tabriz University of Medical Scienses

Full name of responsible person

Dr. Rashidi

Street address

Vice Chancellor for Research, Building No. 2 Tabriz University of Medical Sciences, Golgasht Street

City

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for reaserch, Tabriz University of Medical Scienses

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

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Simin Atashkhoei

Position

Anesthesiologist/ Professor

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Person responsible for scientific inquiries

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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