

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jul 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

Name

Simin Atashkhoei

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3333 3806

##### Email address

atashkhoei@tbzmed.ac.ir

##### 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 Channel 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

Ethics 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

## Sponsors / Funding sources

**1**

### Sponsor

#### Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

#### Full name of responsible person

Dr. Rashidi

#### Street address

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

#### City

Tabriz

### 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, Tabriz 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

Vice chancellor for research, Tabriz University of Medical Sciences

#### Full name of responsible person

Dr. Simin Atashkhoei

#### Position

Anesthesiologist/ Professor

#### Other areas of specialty/work

#### Street address

Al-Zahra Hospital, South Artesh Street

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Vice Chancellor for Research, Tabriz university of Medical sciences

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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*