

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparing the effect of ketamine and remifentanil combination with ketamine and propofol combination on pain, agitation and hemodynamic changes in patients undergoing closed nasal bone reduction

#### Protocol summary

##### Study aim

The purpose of this study is to compare the effect of ketamine and remifentanil combination with ketamine and propofol on pain, agitation and hemodynamic changes in patients undergoing closed nasal bone reduction

##### Design

In this single-blind clinical trial, 70 patients who were candidates for closed nasal bone reduction using randomized 4-block method were assigned into two first and second intervention groups.

##### Settings and conduct

The site of this clinical trial is Kowsar Hospital in Sanandaj. The patients using randomized 4-block method were assigned to two first and second intervention groups. Patients did not know about blocking and were blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included; ASA status of 1, the patient undergoes nose bone closed fracture reduction and age from 18 to 60 years old. Exclusion criteria included; history of hypertension, hyperthyroidism, mental disorders, history of coronary artery disease, and drug use.

##### Intervention groups

In the first intervention group, 0.75 mg/kg of ketamine and 2 µg/kg of remifentanil are injected for induction of anesthesia and in the second intervention group, 0.75 mg/kg ketamine and 1.5 mg/kg propofol are injected for induction of anesthesia.

##### Main outcome variables

The outcomes of this study included pain, agitation and hemodynamic changes.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181127041768N1**  
Registration date: **2018-12-08, 1397/09/17**  
Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-08, 1397/09/17**

Update count: **0**

##### Registration date

2018-12-08, 1397/09/17

##### Registrant information

##### Name

Azade Fathi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3328 2002

##### Email address

a.fathi@muk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2018-12-22, 1397/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of ketamine and remifentanil

combination with ketamine and propofol combination on pain, agitation and hemodynamic changes in patients undergoing closed nasal bone reduction

#### Public title

Evaluating the effect of ketamine and remifentanyl combination with ketamine and propofol on pain and agitation

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

ASA status equal to 1 The patient undergoes nose bone closed fracture reduction Age from 18 to 60 years old.

##### Exclusion criteria:

History of Hypertension Hyperthyroidism Mental disorders History of coronary artery disease Drug use

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients were selected using randomized 4-block method

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Patients were not aware of the grouping.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

###### Street address

Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran

###### City

Sanandaj

###### Province

Kurdistan

###### Postal code

66177-13446

#### Approval date

2018-03-14, 1396/12/23

#### Ethics committee reference number

IR.MUK.REC.1396/374

### Health conditions studied

#### 1

##### Description of health condition studied

Postoperative Pain

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

pain

##### Timepoint

After surgery in the recovery room and every 15 minutes to 2 hours.

##### Method of measurement

Based on Numeric Rating Scale

#### 2

##### Description

Agitation

##### Timepoint

After surgery in the recovery room and every 15 minutes to 2 hours.

##### Method of measurement

Based on Richmond Agitation-Sedation Scale

#### 3

##### Description

Hypertension

##### Timepoint

Every 15 Minutes

##### Method of measurement

Using the vital signs monitoring device

#### 4

##### Description

Heart rate

##### Timepoint

Every 15 Minutes

##### Method of measurement

Using the vital signs monitoring device

### Secondary outcomes

empty

### Intervention groups

## 1

### Description

Intervention group: In the first intervention group, 0.75 mg/kg of ketamine and 2 µg/kg of remifentanyl are injected for induction of anesthesia.

### Category

Treatment - Surgery

## 2

### Description

Intervention group: In the second intervention group, 0.75 mg/kg ketamine and 1.5 mg/kg propofol are injected for induction of anesthesia.

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

### 2

#### Recruitment center

##### Name of recruitment center

Kowsar hospital

##### Full name of responsible person

Azadeh Fathi

##### Street address

Pasdaran St., Kowsar hospital, Sanandaj, Iran

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

66168-12131

##### Phone

+98 87 3361 1233

##### Email

a.fathi@muk.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sanandaj University of Medical Sciences

##### Full name of responsible person

Ebrahim Ghaderi

##### Street address

Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

66177-13446

##### Phone

+98 87 3366 4653

##### Email

ebrahimghaderi@yahoo.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

#### Full name of responsible person

Azadeh Fathi

#### Position

Resident of Anesthesiology

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Anesthesiology

#### Street address

Pasdaran St., Kowsar hospital, sanandaj, Iran

#### City

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#### Province

Kurdistan

#### Postal code

6616812131

#### Phone

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#### Email

a.fathi@muk.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Sanandaj University of Medical Sciences

#### Full name of responsible person

Farzad Sarshivi

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Anesthesiology

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farzadsarshivi@gmail.com

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Part of data on the primary outcomes will be shared.

**When the data will become available and for how long**

Six months after the publication of the results data access is possible.

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Meta-analysis is allowed.

**From where data/document is obtainable**

Dr. Azadeh Fathi via email: A.fathai@muk.ac.ir

**What processes are involved for a request to access data/document**

Three months after the request, the data will be sent.

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

Sanandaj University of Medical Sciences

**Full name of responsible person**

Azadeh Fathi

**Position**

Resident of Anesthesiology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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