

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison Of Infusion Of Midazolam-Ketamine With Isofloran-Remifentanil On Postoperative Pain In Patients Undergoing Rhinoplasty Surgery

#### Protocol summary

##### Summary

This study is a randomized double-blind clinical trial. The aim of this study is Comparison of infusion of midazolam-ketamine with isofloran-remifentanil on postoperative pain in 96 patients 18-40 years old undergoing rhinoplasty surgery. Patients with a history of liver or kidney problems or sensitivity to drugs will be excluded. Patients are randomly divided into two groups. The patients are not aware of the type of drug which received and Evaluation of patients is performed by anesthesiologist who does not know about the protocol of the study. Anesthesia induction in two groups is with 0.05 mg/Kg midazolam, 3 mcg/Kg fentanyl, 2.5 mg/Kg propofol, 0.5 mg/Kg atracurium. Maintenance of anesthesia in the first group is midazolam-ketamine. Maintenance of anesthesia in the second group is isoflurane-remifentanil. After operative the Severity of pain in patients were assessed with a visual analog scale. If patients needed to analgesic drug they received 10 mg pethidine. The amount of analgesic consumption were recorded at 24 hours after surgery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014030116119N2**

Registration date: **2014-11-01, 1393/08/10**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-01, 1393/08/10

##### Registrant information

Name

Reza Akhondzadeh

##### Name of organization / entity

Imam Khomeini Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1221 6504

##### Email address

akhondzadeh-r@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahwaz Jondishapour University of Medical Sciences

##### Expected recruitment start date

2014-07-01, 1393/04/10

##### Expected recruitment end date

2015-01-30, 1393/11/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison Of Infusion Of Midazolam-Ketamine With Isofloran-Remifentanil On Postoperative Pain In Patients Undergoing Rhinoplasty Surgery

##### Public title

The Effect Of Midazolam, Ketamine, Isoflurane And Remifentanil On Postoperative Pain After Rhinoplasty

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: No history of renal, cardiac, hepatic diseases. Exclusion criteria: The control problem of anesthesia during surgery; history of allergy to drugs

used during surgery; prolonged surgery; changing the operation to another type of surgery except rhinoplasty

#### Age

From **18 years** old to **40 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **96**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

To randomization: Consecutive odd and even numbers are assigned to patients. midazolam-ketamine and isofluran-remifentanil are administered to odd and even numbered, respectively.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ahwaz Jondishapour University Of Medical Sciences

##### Street address

Office Of Deputy Research & Technology, Ground Floor, Central Library, Golestan BLvd., Ahwaz Jondishapour University of Medical Sciences, Ahwaz

##### City

Ahwaz

##### Postal code

#### Approval date

2014-05-17, 1393/02/27

#### Ethics committee reference number

ajums.REC.1391.85

## Health conditions studied

### 1

#### Description of health condition studied

Postoperative Analgesia

#### ICD-10 code

Y45

#### ICD-10 code description

complication of medical and surgical care-opioids and

related analgesics

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

in the recovery room and 2,4 ,8 ,16 and 24 hours after surgery

#### Method of measurement

visual analog scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Group1: maintenance of anesthesia with infusion 30-45 mcg/kg/min ketamine and 1.3 mcg/kg/min midazolam and ventilation with 50% nitrous oxide

#### Category

Prevention

### 2

#### Description

Group2: maintenance of anesthesia with 1 mac isoflurane and ventilation with 50% nitrous oxide and infusion 1-2 mcg/kg/min remifentanil

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Reza Akhondzadeh

##### Street address

Department of Anesthesiology, General Operating Room, Second Floor Of The Imam Khomeini Hospital, Shahid Ahwazian St., Ahwaz

##### City

Ahwaz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Ahwaz Jondishapour University of Medical Sciences

**Full name of responsible person**

Nader Saki

**Street address**

Office of Vice chancellor for research, Ahwaz  
 Jondishapour University of Medical Sciences, Ground  
 Floor, central library, Golestan BLvd., Ahwaz  
 Jondishapour University of Medical Sciences, Ahwaz

**City**

Ahwaz

**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, Ahwaz Jondishapour  
 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**

Imam Khomeini Hospital

**Full name of responsible person**

Reza Akhondzadeh

**Position**

Anesthesiologist

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

Department of Anesthesiology, General Operating  
 Room, Second Floor Of The Imam Khomeini Hospital,  
 Shahid Ahwazian St., Ahwaz

**City**

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**Fax****Email**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Imam khomeini Hospital

**Full name of responsible person**

Reza Akhondzadeh

**Position**

Anesthesiologist

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 Room, Second Floor Of The Imam Khomeini Hospital,  
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Pain Research Center

**Full name of responsible person**

Sanaz Nazari

**Position**

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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*