

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

Ahwaz

Postal code**Phone**

00

Fax**Email**

rezaakh@hotmail.com

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

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

Ahwaz

Postal code**Phone**

+98 61 1221 6504

Fax**Email**

rezaakh@hotmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Pain Research Center

Full name of responsible person

Sanaz Nazari

Position

Anesthesia Technician

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

Pain Research Center, Fourth Floor, Imam Khomeini
 Hospital, Shahid Ahwazian St., Ahwaz

City

Ahwaz

Postal code**Phone**

00

Fax**Email**

s.nz1990@yahoo.com

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*