

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of effect of ketamine and lidocaine on prevention of emergence agitation in Rhinoplasty

Protocol summary

Study aim

If we observe the positive effects of the dose of ketamine and lidocaine on the prevention of emergence agitation (EA) and pain after rhinoplasty surgery, this method can be used to prevent EA and postoperative pain in rhinoplasty and other surgeries.

Design

A clinical trial with three groups of control, lidocaine and ketamine with parallel groups, phase 3, randomized, one side blinded on 72 patients, coin flip is used for randomization.

Settings and conduct

All patients referred for elective rhinoplasty surgery who are eligible for the study and have undergone general anesthesia. Operating room of Amirkabir Hospital in Arak. The method of induction of anesthesia will be the same in all three groups 20 minutes before the end of surgery patients in the control group will receive 1 ml of normal saline and patients in the ketamine group / 5. Mg / kg ketamine and patients in the lidocaine group 1.5 mg / kg lidocaine intravenously with similar syringes. After estimation and transfer of the patient to recovery room, the patient's restlessness will be recorded by the RASS scale every 10 minutes until discharge from the recovery by a trained nurse. Also, the amount of postoperative pain will be recorded by the Numerical Pain Measurement Scale (NRS) every 10 minutes.

Participants/Inclusion and exclusion criteria

All patients referred for elective rhinoplasty surgery who are eligible for the study and have undergone general anesthesia.

Intervention groups

Control Group: Placebo Injection Lidocaine group: 1.5mg/kg lidocaine injection Ketamine Group: .5mg/kg Ketamine injection

Main outcome variables

Restlessness when waking up from anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220302054164N1**

Registration date: **2022-04-06, 1401/01/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-06, 1401/01/17**

Update count: **0**

Registration date

2022-04-06, 1401/01/17

Registrant information

Name

Safoora Omidvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3526

Email address

s_omidvar1991@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of ketamine and lidocaine on prevention of emergence agitation in Rhinoplasty

Public title

Comparison of effect of ketamine and lidocaine on prevention of emergence agitation in Rhinoplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Referral for elective rhinoplasty surgery Age 18-45 years
Lack of known allergies to the drugs used in the present study
No pregnancy
No drug addiction
Do not use psychotropic drugs
Perform surgery under general anesthesia
Classification of ASA class, I-II

Exclusion criteria:

Taking painkillers and sedatives 24 hours before surgery
History of heart disease, nervous system, and neurological disorders
Patient with a history of previous rhinoplasty
History of seizures
Duration of anesthesia and surgery more than 2 hours

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is to flip a coin and based on the sample size, the same number of coins will be thrown. If head is observed, the patient will be in the ketamine group and otherwise in the lidocaine group.

Blinding (investigator's opinion)

Single blinded

Blinding description

This randomized study is one side blinded because the patient does not know which treatment or medication he/she is receiving

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical

sciences

Street address

Sardasht

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2022-01-22, 1400/11/02

Ethics committee reference number

IR.ARAKMU.REC.1400.281

Health conditions studied

1

Description of health condition studied

rhinoplasty surgery

ICD-10 code

J95-J95

ICD-10 code description

Intraoperative and postprocedural complications and disorders of the respiratory system, not elsewhere classified

Primary outcomes

1

Description

Restlessness when waking up from anesthesia

Timepoint

During anesthesia until the end of the patient's presence in the recovery room, the patient's vital signs will be measured. Also, during the presence at recovery, the RASS and NRS questionnaires will be filled in.

Method of measurement

After extubation and transfer of the patient to recovery room, the patient's restlessness will be recorded by the RASS scale every 10 minutes until discharge from the recovery by a trained nurse who does not know the patient group. Also, after transferring the patient to recovery room, the amount of postoperative pain will be recorded by the Numerical Pain Measurement Scale (NRS) every 10 minutes.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Lidocaine group: 1.5 mg / kg lidocaine intravenously 20 minutes before surgery completion

Category

Prevention

2

Description

Intervention group: Intervention group: Ketamine group: 5 / . Mg / kg of ketamine 20 minutes before surgery completion

Category

Prevention

3

Description

Control group: 20 minutes before surgery completion to patients in the control group 1 ml of normal saline intravenously

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Fateme Ebrahimi

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Alamolhoda

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3819693181

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Safoora Omidvar

Position

professor

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available