

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effects of analgesia and complications of subcutaneous and intravenous ketamine in closed reduction of nasal fracture

Protocol summary

Study aim

The aim of this study was to compare the effects of analgesia and intravenous and intravenous ketamine in patients with nasal fracture.

Design

In this study, patients with diagnosed nasal fractures will be included in the study. Patients will be divided into 2 groups described. Randomization has not been followed. The sample size for each group would be 32 in total, 64. The study will be conducted in Phase 3. Blood pressure is measured before the injection of the medication. During pain reduction, patients' pain levels will be measured based on the VAS score.

Settings and conduct

The study will be performed at Fatemi Hospital in a randomized, non-blinded, case-control study.

Participants/Inclusion and exclusion criteria

In this study, patients diagnosed with nasal fracture who were admitted for nasal closure in Ardabil Fatemi hospital, after obtaining consent to enter the study and recording their demographic characteristics, will be included in the relevant questionnaires.

Intervention groups

The first group of patients receiving subcutaneous ketamine (0.5 mg / kg) in the anterior forearm 10 minutes before reduction, 7 minutes after midazolam (0.03 mg / kg) and fentanyl (1.5µg / kg). The second group received intravenous ketamine (0.3 mg / kg), followed by midazolam (0.03 mg / kg) and fentanyl (1.5 µg / kg) for 3 minutes.

Main outcome variables

The main variable of the study is the pain scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191011045060N1**

Registration date: **2020-01-26, 1398/11/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-26, 1398/11/06**

Update count: **0**

Registration date

2020-01-26, 1398/11/06

Registrant information

Name

Shaghayegh Delshad Namin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3323 0739

Email address

sh.delshad@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of analgesia and complications of subcutaneous and intravenous ketamine in closed

reduction of nasal fracture

Public title

Comparison of the effects of analgesia and complications of subcutaneous and intravenous ketamine in closed reduction of nasal fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 5 to 60 years Patients with nasal fractures

Exclusion criteria:

Drug sensitivity or anesthesia Pregnancy History of seizures History of hypertension comoncold History of brain trauma

Age

From **5 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

No. 1, Daneshgah Ave

City

Ardabil

Province

Ardabil

Postal code

5613843793

Approval date

2019-08-25, 1398/06/03

Ethics committee reference number

IR.ARUMS.REC.1398.276

Health conditions studied

1

Description of health condition studied

Nasal fracture

ICD-10 code

S02.2XXA

ICD-10 code description

Fracture of nasal bones, initial encounter for closed fracture

Primary outcomes

1

Description

Pain scale

Timepoint

When you enter the recovery ward, then 15 and 30 minutes later

Method of measurement

The pain will be measured on a VAS scale. In this model, pain scores of 0 and the most pain a patient can imagine are recorded with a score of 10.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Intervention group 1: The first group of patients receiving subcutaneous ketamine (0.5 mg / kg) who will be injected into the anterior forearm.

Category

Treatment - Drugs

2

Description

Intervention group: The second group will receive intravenous ketamine (0.3 mg / kg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi hospital

Full name of responsible person

Shagayegh Ddelshad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Parvane Naftchi
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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
Ardabil 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
Ardabil University of Medical Sciences
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Vadood norouzi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The questionnaires will be made available anonymously and with a file number.

When the data will become available and for how long

After completing the study

To whom data/document is available

University professors

Under which criteria data/document could be used

In order to find out how to work in SPSS file, anonymous questionnaires will only be available with file number.

From where data/document is obtainable

Contact Dr. Shaghayegh Delshad E-mail
(sh.delshad@arums.ac.ir)

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

Information is available after contacting Dr. Shaghayegh Delshad and University approval

Comments