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)
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+98 87 3328 2002
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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 remifentanil 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
Sananadj
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 remifentanil 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
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Pasdaran St.,Kowsar hospital, Sanandaj, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Ebrahim Ghaderi
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Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran
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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
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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
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Anesthesiology

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Person responsible for updating data

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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