Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Two Different Doses of Ketamine on byspectral index, hemodynamic changes and mental status of patients undergone on closed nasal bone manipulation operation

Protocol summary

Summary

ketamine is a non barbiturates short acting intravenous anesthetic drug that caused the separative anesthesia like involuntary movements and cataleptic mode. In older patients ketamin is beneficial in emergency trauma and surgery or shock. To determine the efficacy of two doses of ketamine on the byspectral index, hemodynamic changes and mental status of patients undergoing reduction of nasal fracture surgery. A clinical trial study on 80 patients' candidate for closed reduction of nasal fracture surgery, 18 to 59 years old who classified in Class 1 ASA anesthesia is used. People with history of hypertension, epilepsy, hyperthyroid, mental disorders coronary artery were excluded. This form of random allocation was designed to block randomization, in both group, At first, was administered 0.1 mg/kg Sufentanil then 0.2mg/kg Midazolam after that, in control group, anesthetic induction in Group HDK (High Dose Ketamin)was pretreated with ketamine 1 mg/kg and in intervention group, anesthetic induction in Group LDK(Low Dose Ketamin) was pretreated with ketammin 0.5mg/kg. Patient during, exactly after induction by ketamin and after the operation every 15 minutes until 2 hours for efficacy of anesthesia and hemodynamic changes by blood pressure measurement with same manometer, heart rate, BSI (with superficial electrodes on head skin were performed by the same nurse who was blinded to Study medication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012080710471N2**
Registration date: **2012-09-17, 1391/06/27**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-09-17, 1391/06/27

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kurdestan University of Medical Science

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Two Different Doses of Ketamine on byspectral index, hemodynamic changes and mental status of patients undergone on closed nasal bone manipulation operation

Public title

Efficacy of Ketamin on efficiency of anasthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion critria: ASA class I;18-60 years of age;patients undergoing elective closed manipulation operation. Exclusion critria:neurological disorders; a negative effect in communication;history of hypersensitivity towards these drugs; hypertension; epilepsy; hyperthyroidism; psychological disorders; cardiovascular disease; opium addiction.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdestan Local Research Ethics Committee

Street address

Kurdestan University of Medical Science, Pasdaran ave, Azadi sqare

City

Sanandaj

Postal code

Approval date

2010-03-18, 1388/12/27

Ethics committee reference number

11961پ14پ

Health conditions studied

1

Description of health condition studied

Anasthetic Unspecified

ICD-10 code

Y-48.4

ICD-10 code description

Anasthetic Unspecified

Primary outcomes

1

Description

Blood Preasure

Timepoint

during,exactly after induction by ketamin, after the operation every 15 minutes till 2 hours

Method of measurement

blood pressure measurement with same manometer were performed by the same nurse who was blinded to Study medication.

2

Description

Heart Rate

Timepoint

during,exactly after induction by ketamin, after the operation every 15 minutes till 2 hours

Method of measurement

Radial pulse was performed by the same nurse who was blinded to Study medication.

3

Description

BSI

Timepoint

during,exactly after induction by ketamin, after the operation every 15 minutes till 2 hours

Method of measurement

BSI by superfisial electrodes on the head skin.it was explained as an index between 0-100 was performed by the same nurse who was blinded to Study medication.

Secondary outcomes

empty

Intervention groups

1

Description

in intervention group, At first was administered 0.1 mg/kg Sufentanil then 0.2mg/kg Midazolam and at last anesthetic induction with ketammin 0.5mg/kg.

Category

Treatment - Drugs

2

Description

in control group,At first was administered 0.1 mg/kg Sufentanil then 0.2mg/kg Midazolam and at last anesthetic induction ketamine 1 mg/kg.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Toohid Hospital
Full name of responsible person
Milad Masaeli
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kurdestan University of Medical Science
Full name of responsible person
Fardin Gharibi
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Kurdestan University of Medical Sience, Pasdaran avenue,Azadi sqare
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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
Kurdestan University of Medical Science
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

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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