

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

###### Name

Milad Masaeli

###### Name of organization / entity

Kurdistan University Of Medical Sciences

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Iran (Islamic Republic of)

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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**

11961۲14۲

## **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

**Street address****City**

Snandaj

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kurdistan University of Medical Science

**Full name of responsible person**

Fardin Gharibi

**Street address**Kurdistan University of Medical Science, Pasdaran  
avenue, Azadi square**City**

Sanandaj

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kurdistan 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****Contact****Name of organization / entity**Student of Research Committee, Kurdistan University  
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Milad Masaeli

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drmilmas@yahoo.com**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**Assistant Professor of Anesthesiology, Department of  
Anesthesia, Beesat Hospital, Kurdistan University**Full name of responsible person**

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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*