

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Comparison of dexmedetomidine-alfentanyl vs ketamine-alfentanyl for closed reduction of nasal bone fracture

#### Protocol summary

##### Study aim

Comparison of dexmedetomidine-alfentanyl vs ketamine-alfentanyl for closed reduction of nasal bone fracture

##### Design

Randomized double blinded clinical trial with two factorial group

##### Settings and conduct

Sixty patients, 15-40 years old, who were scheduled for close reduction of nasal bone fracture with sedation in Ahvas Imam khomeini hospital, were enrolled in this randomized and double-blinded study. Patients were randomly assigned into two groups of 30 patients. Group A received dexmedetomidine-alfentanyl and Group B received ketamine-alfentanyl intravenously

##### Participants/Inclusion and exclusion criteria

fracture time less than 72 hours and no comorbidity

##### Intervention groups

dexmedetomidine-alfentanyl group and ketamine-alfentanyl group

##### Main outcome variables

VAS pain score, sBp, dBp, MAP, heart rate, recovery time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191127045530N1**

Registration date: **2019-12-31, 1398/10/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-31, 1398/10/10**

Update count: **0**

##### Registration date

2019-12-31, 1398/10/10

##### Registrant information

##### Name

Fahimeh Elyasinia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3392 5882

##### Email address

elyasinia.fahimeh@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-11-24, 1398/09/03

##### Expected recruitment end date

2020-01-23, 1398/11/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of dexmedetomidine-alfentanyl vs ketamine-alfentanyl for closed reduction of nasal bone fracture

##### Public title

Comparison of dexmedetomidine-alfentanyl vs ketamine-alfentanyl for closed reduction of nasal bone fracture

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

fracture less than 72 hours 15 - 40 years range

##### Exclusion criteria:

co morbidity

##### Age

From **15 years** old to **40 years** old

##### Gender

Both

## Phase

3

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: 60

### Randomization (investigator's opinion)

Randomized

### Randomization description

Our method is simple randomization and assign subjects into two groups A and B. We assign subjects to each group randomly based on last digit of his or her number of hospital's file for every assignment. We put Even numbers into group A dexmedetomidine-alfentanyl and odd numbers into group B ketamine-alfentanyl.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

volunteers are not aware of the type of drugs are used for anesthesia .Also data collectors and data analysts do their job only with the name of A and B for both groups and about the drug content of groups are unaware.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz jondishapour University of Medical Sciences

##### Street address

No233, Isfahan Ave; golestan Blvd; Ahvaz town

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6136834498

#### Approval date

2019-11-23, 1398/09/02

#### Ethics committee reference number

IR.AJUMS.REC.1398.624

## Health conditions studied

### 1

#### Description of health condition studied

Nasal bone fracture

### ICD-10 code

S02.2XXA

### ICD-10 code description

Fracture of nasal bones, initial encounter for closed fracture

## Primary outcomes

### 1

#### Description

systolic blood pressure

#### Timepoint

Before intervention,1 min later,5 min later,15 min later,recovery,2 hours later,4 hours later

#### Method of measurement

sphygmomanometer

### 2

#### Description

diastolic blood pressure

#### Timepoint

Before intervention,1 min later,5 min later,15 min later,recovery,2 hours later,4 hours later

#### Method of measurement

sphygmomanometer

### 3

#### Description

mean arterial pressure

#### Timepoint

Before intervention,1 min later,5 min later,15 min later,recovery,2 hours later,4 hours later

#### Method of measurement

sphygmomanometer

### 4

#### Description

pain score

#### Timepoint

Before intervention,1 min later,5 min later,15 min later,recovery,2 hours later,4 hours later

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Awakening time

#### Timepoint

Awakening time

#### Method of measurement

Ramsay sedation score

## 2

### Description

Discharge from recovery

### Timepoint

Discharge from recovery

### Method of measurement

Modified Alderete Score

## 3

### Description

agitation

### Timepoint

Before intervention,min 1 ,min 5 ,min 15,recovery,2 hours later,4 hours later

### Method of measurement

Modified observers assessment of alertness/sedation scale(MOAA/S)

## 4

### Description

Satisfaction of patient and surgeon

### Timepoint

min1 ,min5,min 15,recovery ,2 hours later,4 hours later

### Method of measurement

7 point likert like verbal rating scale

## Intervention groups

### 1

#### Description

Intervention group: dexmedetomidine 1 µg/kg Exir-alfentanil 8µg/kg Daroupakhsh

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: ketamine mg/kg 1 Exir-alfentanil 8µg/kg Daroupakhsh

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ahvaz Imam khomeini hospital

##### Full name of responsible person

Fahimeh Elyasinia

##### Street address

Ahvaz. shohada square

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6136834498

##### Phone

+98 61 3292 3985

##### Email

Elyasinia.fahimeh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mohammad Badavi

##### Street address

Ahvaz, Golestan Blvd

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6193673111

##### Phone

+98 61 3336 1544

##### Email

Elyasinia.Fahimeh@gmail.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Fahimeh Elyasinia

##### Position

assistant

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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Assistant  
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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

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

### 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