

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of general anesthesia with isoflurane/N2O and propofol/alfentanil on optimal extubation in mandibular fractures with arch bar

#### Protocol summary

##### Summary

The purpose of this study is Comparison of general anesthesia with isoflurane/N2O and propofol/alfentanil on optimal extubation in mandibular fractures with arch bar. Therefore, 60 patients with mandibular fracture with arch bar with age more than 15years old and ASA I that have not history of hypertension or use of anti hypertensive drug or frequent use of narcotic drug were divided into two groups. In the first group used of combination propofol / alfentanil and in the second group used of combination of isoflurane / N2O for maintenance of anesthesia and finally, hemodynamic status, nausea and vomiting and the patient's condition in terms of comfort during extubation was been evaluated.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015072412642N16**

Registration date: **2015-08-13, 1394/05/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-08-13, 1394/05/22

##### Registrant information

###### Name

Majid Golestani Eraghi

###### Name of organization / entity

Shahid Beheshti University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 3336 0547

##### Email address

dr.golestani@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Qazvin University of Medical Sciences

##### Expected recruitment start date

2014-11-30, 1393/09/09

##### Expected recruitment end date

2015-05-31, 1394/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of general anesthesia with isoflurane/N2O and propofol/alfentanil on optimal extubation in mandibular fractures with arch bar

##### Public title

Effect of General anesthesia on optimal extubation in mandibular fractures

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion Criteria: Patient with ASA I; Age more than 15 years old. Exclusion Criteria: Patient with history of use of narcotic; Patient with history of use of anti hypertensive drug; Patients with hypertension; Patient with age more than 50 years old.

##### Age

From **15 years** old to **50 years** old

##### Gender

Both

## Phase

2

### Groups that have been masked

No information

### Sample size

Target sample size: 60

### Randomization (investigator's opinion)

N/A

### 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

Ethics committee of Qazvin University of Medical Sciences

##### Street address

Shahid Bahonar Boulvar

##### City

Qazvin

##### Postal code

#### Approval date

2013-04-22, 1392/02/02

#### Ethics committee reference number

28/20/7239

## Health conditions studied

### 1

#### Description of health condition studied

mandible fracture surgery

#### ICD-10 code

S02.6

#### ICD-10 code description

Fracture of mandible

## Primary outcomes

### 1

#### Description

Blood Pressure

#### Timepoint

From 5 minutes before induction to 15 minutes after induction with 5 minute intervals.

#### Method of measurement

By mercury sphygmomanometer in mmHg

### 2

#### Description

Heart rate

#### Timepoint

From 5 minutes before induction to 15 minutes after induction with 5 minute intervals.

#### Method of measurement

By pulse oximetry in terms of number of minutes.

### 3

#### Description

Comfort during extubation

#### Timepoint

From 5 minutes before induction to 15 minutes after induction with 5 minute intervals.

#### Method of measurement

According scored based on the elevation of the arm or leg and pressing hand of doctor

## Secondary outcomes

### 1

#### Description

Nausea

#### Timepoint

From 5 minutes before anesthesia to 24 hours after surgery

#### Method of measurement

According to the saying patient

### 2

#### Description

Vomitting

#### Timepoint

From 5 minutes before anesthesia to 24 hours after surgery

#### Method of measurement

According to the saying patient

## Intervention groups

### 1

#### Description

In the first group after the induction maintenance of anesthesia will done in combination with a dose of 100 micrograms per kilogram body weight in minute propofol and one micrograms per kilogram body weight in minute alfentanyl.

#### Category

Treatment - Drugs

### 2

#### Description

In the first group after the induction maintenance of anesthesia will done in combination with 1%isoflurane and 50/50 mix oxygen and nitrous oxide

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid Rajaee hospital in Qazvin

**Full name of responsible person**

Majid Golestani Eraghi

**Street address**

Padegan Ave

**City**

Qazvin

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Qazvin University of Medical Sciences

**Full name of responsible person**

Taghi Naserpoor Farivar

**Street address**

Shahid Bahonar Boulvar

**City**

Qazvin

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for research of Qazvin University of Medical Sciences

**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

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Department of Anesthesiology, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza Jahangiri Fard

**Position**

Fellowship of Cardiac Anesthesia

**Other areas of specialty/work**

**Street address**

Daneshjoo Ave, Velenjak

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+98 21 2712 2525

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alirezajahangiri@sbmu.ac.ir

**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Anesthesia group, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Majid Golestani Eraghi

**Position**

Fellowship specialty intensive care

**Other areas of specialty/work**

**Street address**

Masih Daneshvari Hospital, Darabad Ave

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**Web page address**

## 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*