

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 alfentanil.

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

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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

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Person responsible for updating data

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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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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