

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison the effects of general anesthesia with isoflurane-nitrous oxide versus propofol-alfentanil on the desirable condition of extubation of patients with arch bar in mandibular fracture surgery

Protocol summary

Summary

The aim of this study was comparison the effects of anesthesia with isoflurane-N₂O versus propofol-alfentanil on the desirable extubation condition of patients with arch bar in mandibular fracture surgery. In this randomized double blinded clinical trial study, sixty patients who scheduled for fixing of mandibular fracture with arch bar had been studied. Inclusion criteria were age 15-50 years old; ASA class I; presence of mandibular fracture and patient consent. Exclusion criteria of the study were consumption of narcotic; sedative or antihypertensive drugs and the presence of sensitivity to drugs used in this study such as propofol or narcotics. The patients were divided randomly in two groups. Drugs used for premedication and induction of general anesthesia were the same in the two groups. For maintenance of general anesthesia, one group received propofol (100 µg/kg/min) with alfentanil (1 µg/kg/min) but patients in the other group received isoflurane 1.2% (1 MAC) with N₂O-O₂ (50%-50%). Optimal condition for extubation was evaluated by the presence of bucking, patients' cooperation for eye opening, head elevation, legs elevation and hand grasping for five seconds. Finally in the presence of above conditions, patients were extubated. Blood pressure and heart rate of the patients were measured every five minutes from five minutes before induction of anesthesia until fifteen minutes after extubation. After extubation, incidence of nausea and vomiting were determined and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405037695N4**

Registration date: **2014-06-04, 1393/03/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-04, 1393/03/14

Registrant information

Name

Seyedeh Masoumeh Hosseini Valami

Name of organization / entity

Qazvin University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 1334 8419

Email address

smhosseiniv@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of general anesthesia with isoflurane-nitrous oxide versus propofol-alfentanil on the desirable condition of extubation of patients with arch bar in mandibular fracture surgery

Public title

Comparison the effects of general anesthesia with isoflurane-nitrous oxide versus propofol-alfentanil on desirable condition of extubation of patients with arch bar in mandibular fracture surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: mandibular fracture surgery with arch bar; age 15-50 years old; ASA class I; patients' consent
Exclusion criteria: consumption of narcotic; sedative or antihypertensive drugs; presence of hypertension or impairment of consciousness; sensitivity to isoflurane, nitrous oxide, propofol and alfentanil

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethics Committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blv, Qazvin

City

Qazvin

Postal code

3419759811

Approval date

2011-12-26, 1390/10/05

Ethics committee reference number

28/20/7239

Health conditions studied

1

Description of health condition studied

Mandibular fracture

ICD-10 code

S02.6

ICD-10 code description

Fracture of mandible

Primary outcomes

1

Description

Desirable condition for endotracheal extubation

Timepoint

After endotracheal extubation in operating room

Method of measurement

By the presence of bucking, patients' cooperation for eye opening, head elevation, legs elevation and hand grasping for five seconds

Secondary outcomes

1

Description

Blood pressure and heart rate

Timepoint

Every five minutes from five minutes before induction of anesthesia until fifteen minutes after extubation

Method of measurement

By noninvasive blood pressure and cardiovascular monitoring

2

Description

Nausea, vomiting

Timepoint

After endotracheal extubation and in recovery room

Method of measurement

Visual

Intervention groups

1

Description

Patients in one group received propofol (100 µg/kg/min) with alfentanil (1 µg/kg/min).

Category

Treatment - Drugs

2

Description

Patients in another group received isoflurane 1.2% (1 MAC) with N2O-O2 (50%-50%). We did not have any control group in this study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Rajaee Hospital

Full name of responsible person

Dr. Seyed Abbas Hosseini Jahromi

Street address

Shaheed Rajaee Hospital, Padegan street

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research Qazvin University of Medical Sciences

Full name of responsible person

Dr. Saeid Asefzadeh

Street address

Qazvin University of Medical Sciences, Shahid Bahonar street

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 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

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyedeh Masoumeh Hosseini Valami

Position

Anesthesiologist, Associate Professor

Other areas of specialty/work

Street address

Qazvin University of Medical Sciences, Shaheed Bahonar Street

City

Qazvin

Postal code

Phone

+98 281336001

Fax

Email

smhosseiniv@qums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Abbas Hosseini Jahromi

Position

Anesthesiologist, Associate Professor

Other areas of specialty/work

Street address

Qazvin University of Medical Sciences, Shaheed Bahonar street

City

Qazvin

Postal code

Phone

+98 28 1333 6001

Fax

Email

sahosseiniij@qums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Abbas Hosseini Jahromi

Position

Anesthesiologist, Associate Professor

Other areas of specialty/work

Street address

Qazvin University of Medical Sciences, Shaheed Bahonar street

City

Qazvin

Postal code

Phone

+98 28 1333 6001

Fax

Email

sahosseiniij@qums.ac.ir

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