Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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-alfentanyl 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

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Name of organization / entity

Qazvin University Of Medical Sciences

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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 endotrcheal extuation
Timepoint
After endotrcheal etubation 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
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Qazvin University of Medical Sciences, Shahid Bahonar street
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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

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Person responsible for updating data

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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