

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of Anesthesia effects with isoflurane and propofol on postoperative shivering in patients undergoing rhinoplasty surgery in Imam Khomeini Hospital, Ahwaz in 1390

Protocol summary

Summary

In a clinical trial, double-blind 70 patients 18 to 65 years with ASA I or II that undergoing rhinoplasty surgery were studied with approval of the ethics committee. After informed consent was given, patients were randomly allocated into two groups according to a table of random numbers. Patients were randomized assign to two groups receiving propofol(n=35) and isoflurane(n=35). Inclusion criteria were elective rhinoplasty surgery, in the range of 18-65 years old and duration of surgery between 1-3 hours. Exclusion criteria included emergency surgery, history of seizures, a history of Parkinson's or any other disease that can cause shivering. History of amphetamine drugs or sedatives, history of alcohol or drug addiction, blood transfusion or blood products during anesthesia, consumption of vasoactive drugs during anesthesia and existence of active infection prior to anesthesia. The tympanic membrane temperature, taken to present core temperature. The room temperature was kept constant too. The minute ventilation was adjusted to maintain an end-tidal carbon dioxide concentration of 35 to 45 mmHg. At the end of the operation all anesthetic gases were closed and residual paralysis was reversed with atropine 0/02 mg/kg and neostigmine 0/05 mg/kg. After anesthesia shivering in patients with visual assessment scale shivering was measured by a trained. Since the patient wake up an hour later the occurrence and classify of shivering were assessed by one of the investigators who was unaware of the anesthetic agent given to the patient. If grade 3 or 4 had the shivering, the patient was treated with intravenous pethidine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112178443N1**

Registration date: **2012-05-17, 1391/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-17, 1391/02/28

Registrant information

Name

Mostafa Fatahi

Name of organization / entity

Ahvaz Jondishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2011-04-04, 1390/01/15

Expected recruitment end date

2012-01-05, 1390/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Anesthesia effects with isoflurane and

propofol on postoperative shivering in patients undergoing rhinoplasty surgery in Imam Khomeini Hospital, Ahwaz in 1390

Public title
Effects of Isoflurane and Propofol on postoperative shivering

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Rhinoplasty surgery; in the range of 18-65 years old; duration of surgery between 1-3 hours.
Exclusion criteria: Emergency surgery; history of seizures; a history of Parkinson's or any other disease that can cause shivering; History of amphetamine drugs or sedatives; history of alcohol or drug addiction; blood transfusion or blood products during anesthesia; consumption of vasoactive drugs during anesthesia; existence of active infection prior to anesthesia

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

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
Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz, Bulvar Golestan

City
Ahvaz

Postal code
6135833777

Approval date
2012-03-04, 1390/12/14

Ethics committee reference number
eth.s-001

Health conditions studied

1

Description of health condition studied

Post operative shivering

ICD-10 code

t88.5

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Shivering

Timepoint

Post operative

Method of measurement

Visual assessment scale

Secondary outcomes

1

Description

time of shivering

Timepoint

post operative

Method of measurement

observation

Intervention groups

1

Description

first group drug propofol Intravenously during the operation (mg/kg/h 10-5)

Category

Treatment - Drugs

2

Description

second group Isoflurane inhaled during the operation with a maintenance dose 0.5%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mr sakhaee

Street address

farhangshahr
City
ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
mohandes oraki
Street address
Commite Tahghighati Daneshjuee
City
Ahvaz
Grant name
2500000
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapur 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

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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