Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The cumulative incidence of awareness during anesthesia comparing isoflorane - based versus propofol with alfentanil (TIVA) anesthesia

Protocol summary

Summary

Objectives: The study aimed to investigate the methods for better and less awakening complication in the patients by comparing two general anesthesia (the gas isoflurane anesthesia and mixture injection of propofol and alfentanil). Study design: Double-blind for the patients and investigators, randomized , one trial study. Study setting and conduct: All patients will be under the same conditions of induction of general anesthesia and mechanical ventilation. In the two groups, two different drug will use to sustain anesthesia. The studied patients in two stages will be under the investigation. The standard questionnaire designed by Brice., 1970 will use by people who are unaware of the type of used drugs to assess the presence of awareness during anesthesia. Participants including major eligibility criteria: Volunteer surgery patients in the age group 16 to 70 years old. Major exclusive criteria: Patients which before anesthesia does not able to speak;patients who are not able to talk in the recovery room after anesthesia;severely ill;suspected under coma patients which brought to the operating room; patients with less than 4 hours staying after surgery in the hospital; mental illness and those who are taking psychiatric drugs. Sample: Two groups of 200 patients. Interventions: The first group to sustain anesthetic will inhale isoflurane gas and the second group will inject such mixture of the proposal and alfentanil. The intervening time: After induction of general anesthesia and mechanical ventilation in the operation room. Variable of main outcome: Intraoperative awakening is an independent continual variable and drugs are as the independent nominal variant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012826234N1**

Registration date: **2016-06-10, 1395/03/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-10, 1395/03/21

Registrant information

Name

Forough Rasekhi

Name of organization / entity

University Of Medical Sciences Shiraz

Country

Iran (Islamic Republic of)

Phone

+98 937 928 3620

Email address

rasekhif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

University of Medical Sciences Shiraz(international branch).

Expected recruitment start date

2016-05-09, 1395/02/20

Expected recruitment end date

2016-07-10, 1395/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The cumulative incidence of awareness during anesthesia comparing isoflorane - based versus propofol with alfentanil (TIVA) anesthesia

Public title
The cumulative incidence of awareness during anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: age group 16 to 70 years; all in ASA class III, II, I . Exclusion criteria: Patients under 16 and over 70 years; patients before anesthesia, does not have full consciousness or not able to speak; Patients in the recovery room after anesthesia was not able to talk;Very ill patients with suspected and coma brought to the operating room;Patients who develop postoperative hospital stay of less than 4 hours;Mental illness and those who are taking psychiatric drugs.
Age
From **16 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **400**
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 University of Medical Sciences Shiraz(international branch)
Street address
University of Mdical Sience Shiraz(international branch),injuries and burn hospital entrance, 3rd km of sadra road
City
Shiraz
Postal code
00987144716699
Approval date
2016-03-06, 1394/12/16
Ethics committee reference number
IR.SUMS.RET.1394.220

Health conditions studied

1

Description of health condition studied
History of intraoperative awareness under general anesthesia
ICD-10 code
Z91.89
ICD-10 code description
Personal history of other specified risk-factors, not elsewhere classified

Primary outcomes

1

Description
Awareness during anesthesia
Timepoint
In two stages (in the recovery room and 4 hours after the end of the operation) will be under the investigation
Method of measurement
The standard questions designed by Brice., 1970 will use to assess the presence of awareness during anesthesia

2

Description
The pain feeling during anesthesia
Timepoint
In two stages (in the recovery room and 4 hours after the end of the operation) will be under the investigation
Method of measurement
The standard questions designed by Brice., 1970 will use to assess the presence of awareness during anesthesia

Secondary outcomes

1

Description
Duration of surgery
Timepoint
In the operation room.
Method of measurement
the standard question designed by Brice., 1970 will use to assess the presence of awareness during anesthesia

Intervention groups

1

Description
The first group Isofloran: 0.5-1 percent gas inhalation. After general anesthesia.
Category
Prevention

2

Description
The second group Mixture of propofol and alfentanil: 100 µg / kg / min of Propofol and 1.5 µg/kg/min of Alfentanil. injection after general anesthesia.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Motahhari Hospital

Full name of responsible person
Hamidreza Bahmani

Street address
Shahid Motahhari Hospital,Moallem sq.Marvdasht

City
Marvdasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Medical Sciences Shiraz (International Branch)

Full name of responsible person
Mohammad Foroutan

Street address
Department of Anesthesiology,Shahid Motahhari Hospital,Moallem sq,Marvdasht

City
Marvdasht

Grant name

Grant code / Reference number

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

Title of funding source
University of Medical Sciences Shiraz (International Branch)

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
University of Medical Sciences Shiraz

Full name of responsible person
Hamidreza Bahmani

Position
Anesthesiologist,Assistant Professor

Other areas of specialty/work

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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