

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### The cumulative incidence of awareness during anesthesia comparing isoflurane - 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 isoflurane - 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

#### Street address

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

#### City

Marvdasht

#### Postal code

7187835651

#### Phone

+98 71 3230 5410

#### Fax

+98 71 3230 5410

#### Email

Pencillin2002@yahoo.com

#### Web page address

## Person responsible for scientific 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

#### Street address

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

#### City

Marvdasht

#### Postal code

7187835651

#### Phone

+98 71 3230 5410

#### Fax

+98 71 3230 5410

#### Email

Pencillin2002@yahoo.com

#### Web page address

## Person responsible for updating data

### 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

#### Street address

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

#### City

Marvdasht

**Postal code**

7187835651

**Phone**

+98 71 3230 5410

**Fax**

+98 71 3230 5410

**Email**

Pencilin2002@yahoo.com

**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*