

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 2026

### Comparison of inhalation anesthesia by isoflurane and intravenous anesthesia by propofol for laparoscopic cholecystectomy surgery

#### Protocol summary

##### Summary

The aim of this study is to compare between intravenous anesthesia using propofol and isoflurane inhalation anesthesia for laparoscopic cholecystectomy. In this double blind clinical trial, 60 patients who undergo laparoscopic cholecystectomy using general anesthesia in Imam Khomeini Hospital are randomly divided into two groups of 30 person (the first group inhalation anesthesia with isoflurane and the second group intravenous anesthesia using propofol). Before anesthesia induction, all patients will receive 7ml/kg normal saline. In maintenance of anesthesia, for the first group isoflurane 1.5% and for the second group propofol 100µg/kg/min will administer. In both group, hemodynamic status, time of awakening from the anesthesia, and in the recovery in terms of the incidence of nausea and vomiting and the recovery time of clearance will be evaluated. An investigator blinded to the group assignment of the patients will assess the incidence and severity of hoarseness one day after surgery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014080715795N1**

Registration date: **2015-01-23, 1393/11/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-01-23, 1393/11/03

##### Registrant information

##### Name

babak sabzivand

##### Name of organization / entity

ardabil medical university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 88 13472

##### Email address

b.sabzivand@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ardabil University of Medical Sciences

##### Expected recruitment start date

2014-05-22, 1393/03/01

##### Expected recruitment end date

2014-11-22, 1393/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of inhalation anesthesia by isoflurane and intravenous anesthesia by propofol for laparoscopic cholecystectomy surgery

##### Public title

Comparison of inhalation anesthesia by isoflurane and intravenous anesthesia by propofol for laparoscopic cholecystectomy surgery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: laparoscopic cholecystectomy; aged 15-80 years; ASA class I and II Exclusion criteria of the study: drug allergy; drug addiction; common cold; heart disease, kidney disease and hypertension; patient dissatisfaction; sedative drugs

**Age**

From **15 years** old to **80 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**

Ardabil University of Medical Science

**Street address**

Ardabil University of Medical Science, Ardabil

**City**

Ardabil

**Postal code****Approval date**

2014-02-09, 1392/11/20

**Ethics committee reference number**

arums.rec.92.30

**Health conditions studied****1****Description of health condition studied**

Inhaled anaesthetics

**ICD-10 code**

Y48

**ICD-10 code description**

Inhaled anaesthetics

**Primary outcomes****1****Description**

Duration of discharge from recovery

**Timepoint**

After entering recovery

**Method of measurement**

Obtain recovery discharge criteria

**Secondary outcomes****1****Description**

Blood pressure

**Timepoint**

Every 5 min during anesthesia.

**Method of measurement**

Pressure gauge

**2****Description**

Heart rate

**Timepoint**

Every 5 min during anesthesia.

**Method of measurement**

ECG monitor

**3****Description**

Time of Awakening

**Timepoint**

After discontinuation of anesthetic drugs

**Method of measurement**

Obey orders

**4****Description**

Hoarseness

**Timepoint**

In the first 24 hours after surgery

**Method of measurement**

According to the patient and their relatives.

**5****Description**

Nausea and vomiting

**Timepoint**

In the first 24 hours after surgery

**Method of measurement**

According to the patient and carers

**Intervention groups****1****Description**

7ml/kg normal saline with Isofluran 1.5%

**Category**

Treatment - Drugs

## 2

### Description

7ml/kg normal saline with Propofol 100µg/kg/min

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ardabil's Imam Khomeini Hospital

##### Full name of responsible person

##### Street address

##### City

Ardabil

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ardabil University of Medical Sciences

##### Full name of responsible person

Dr. Akbar Pirzadeh

##### Street address

School of Medicine, Ardabil University of Medical Sciences, Ardabil, Iran

##### City

Ardabil

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

##### Full name of responsible person

Dr. Masood Entezariasl

##### Position

Professor of Anesthesiology

##### Other areas of specialty/work

#### Street address

Fatemy Hospital, Ardabil University of Medical Sciences

#### City

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#### Postal code

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+98 45 3325 1688

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Ardabil University of Medical Sciences

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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*