

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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

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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