Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 isofluran 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 inhalationl anesthesia with isofluran 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 isofluran 1.5% and for the second group propofol 100µg/kg/min will administer. In both group, hemodinamic 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 cholecystectom; 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
Ardabil
Postal code
Phone
+98 45 3325 1688
Fax
Email
m.entezari@arums.ac.ir
Web page address

Person responsible for scientific 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
Ardabil
Postal code
Phone
+98 45 3325 1688
Fax
Email
m.entezari@arums.ac.ir
Web page address

Person responsible for updating data

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
Ardabil
Postal code
Phone
+98 45 3325 1688
Fax
Email
m.entezari@arums.ac.ir
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