

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The Comparison of inhaled and intravenous anesthesia on depth of anesthesia and hemodynamic changing in Cholecystectomy Laparoscopic.

Protocol summary

Summary

Purpose: Study of effect of two inhalant and venous anesthesia on depth of anesthesia and hemodynamic changing in laparoscopic cholecystectomy. Study design: block Randomized, double-blind, placebo without control, Single Central The study population: Our study population consisted of patients 20-40 years candidate for laparoscopic cholecystectomy hospitalized Shohada Hospital Ashaier in Khorram Abad. Inclusion criteria: All patients 20 to 40 years undergoing laparoscopic cholecystectomy referred to Shohada hospital in Khorramabad in the second half of 2015. Exclusion criteria: Lack of consent to participate in research projects, heart problems, allergies to eggs, a history of sensitivity to anesthesia, conversion laparoscopic surgery to open surgery of cholecystectomy, high blood pressure, history of diabetes. The sample size: 92 Patients were randomized to two groups of blocks allocated: Group T to receive intravenous anesthesia And V group to receive inhalation anesthesia. In the operating room patients catheterized and intravenous fluids injected. Prodrug is contains 2 ml narcotic sufentanil and 2 mg midazolam. Induction of anesthesia is done by sodium thiopental and atracurium, Then intubation is performed, Changes in blood pressure and heart rate and depth of anesthesia of patients constantly monitoring, Maintenance of anesthesia in Group T perform with propofol 100 micrograms per kilogram of body weight per minute and in Group v with Sevoflurane 1.2%, By neostigmine and atropine awakening is done. The main outcomes: blood pressure, heart rate, depth of anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092716516N2**

Registration date: **2015-11-25, 1394/09/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-25, 1394/09/04

Registrant information

Name

Sadeghe Nadri

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3322 3004

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Lorestan University of Medical Sciences

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2016-01-05, 1394/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of inhaled and intravenous anesthesia on depth of anesthesia and hemodynamic changing in Cholecystectomy Laparoscopic.

Public title

The Comparison of inhaled and intravenous anesthesia on depth of anesthesia and hemodynamic changing in Cholecystectomy Laparoscopic.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:All patients 20 to 40 years undergoing laparoscopic cholecystectomy referred to Shohada hospital in Khorramabad in the second half of 1394.

Exclusion criteria:Lack of consent to participate in research projects, heart problems, allergies to eggs, a history of sensitivity to anesthesia, conversion laparoscopic surgery to open surgery, cholecystectomy, high blood pressure, history of diabetes.

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Method randomization: block Randomized

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Lorestan,Khorramabad,Lorestan University of Medical Sciences

City

Khorramabad

Postal code

381251698

Approval date

2015-09-22, 1394/06/31

Ethics committee reference number

LUMS.REC.1394.24

Health conditions studied

1

Description of health condition studied

General anesthesia

ICD-10 code

K80-K87

ICD-10 code description

Disorders of gallbladder, biliary tract and pancreas

Primary outcomes

1

Description

blood pressure

Timepoint

Before induction of anesthesia, after premedication injection, after induction of anesthesia, after intubation, during surgery four times, after extubation.And with an interval of every 15 minutes.

Method of measurement

Millimeters of mercury using a sphygmomanometer

2

Description

heart rate

Timepoint

Before induction of anesthesia, after premedication injection, after induction of anesthesia, after intubation, during surgery four times, after extubation. And with an interval of every 15 minutes.

Method of measurement

Depending on the number of beats per minute monitoring device

3

Description

Depth of Anesthesia

Timepoint

Before induction of anesthesia, after premedication injection, after induction of anesthesia, after intubation, during surgery four times, after extubation.And with an interval of every 15 minutes.

Method of measurement

Based on the electrical brain waves and by BIS device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the operating room patients catheterized and intravenous fluids injected .Prodrug is contains 2 ml narcotic sufentanil and 2 mg

midazolam. Induction of anesthesia is done by sodium thiopental and atracurium, Then intubation is performed, In this group (Group T), maintenance of anesthesia perform with propofol 100 mg per kg of body weight per minute. Manufacturer: pharmaceutical company of dongkook, Manufactured by country of Korea

Category

Treatment - Surgery

2**Description**

Control group: In the operating room patients catheterized and intravenous fluids injected .Prodrug is contains 2 ml narcotic sufentanil and 2 mg midazolam. Induction of anesthesia is done by sodium thiopental and atracurium, Then intubation is performed, In this group (Group v), maintenance of anesthesia perform withwith Sevoflurane 1.2%. Manufacturer: pharmaceutical company of BAXTER, Manufactured by country of GUAYAMA

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada hospital

Full name of responsible person

S. Nadri doctor, a specialist in anesthesia, Assistant Professor

Street address

Lorestan, Khorramabad, Shohada hospital

City

Khorramabad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of lorestan University of Medical Sciences

Full name of responsible person

dr. morovvat taheri kalani, Vice Chancellor for research of lorestan University of Medical Sciences

Street address

Vice Chancellor for research of lorestan University of Medical Sciences, 5 km road Boroujerd Khorramabad

City

Khorramabad

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of lorestan 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**

Deputy of Research, Lorestan University of Medical Sciences

Full name of responsible person

Farzad Mohammadi

Position

medical student

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General anesthesia specialist, assistant professor

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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