Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the Effect of Propofol and Isoflurane on Hemodynamics Parameters and Stress Response Hormones during Laparoscopic Cholecystectomy

Protocol summary

Study aim

Comparison the effect of propofol and isoflurane on hemodynamics parameters and stress response hormones during laparoscopic cholecystectomy.

Design

Patients are randomly divided into two intervention groups and the study is design as a randomised, parallel group trial with single blinded outcome assessment.

Settings and conduct

Seventy patients candidate of laparoscopic cholecystectomy in age group 20 to 60 years are randomly divided into intervention (1) and (2) group. The combination of midazolam (0.05 mg/kg), fentanyl (2 µg/kg), sodium thiopental (4 mg/kg), atracurium (0.5 mg/kg) is used to induce anesthesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients with symptomatic gallstone disease or acute cholecystitis, patients without inside or outside biliary tract dilatation and American Society of Anesthesiologists (ASA) classification I , II; The exclusion criteria are obesity patients with class II or III (BMI>35), patients with chronic liver disease, diabetes, renal failure, endocrine problems, rheumatoid arthritis, cardiovascular disease or malignancy, patients receiving drugs with known effects on sympathetic response or hormone secretion, patients receiving benzodiazepines and pregnant or lactating mothers.

Intervention groups

In the Intervention group (1), intravenous injection of propofol 50-150 µg/kg/min is performed and in the intervention group (2), isoflurane with mac: 1.28% atm/mmhg is vaporized and patients inhale.

Main outcome variables

Mean arterial pressure and heart rate in time of starting the operation, every 5 minutes during the time between start of surgery till the completion of the surgical operation and 20 minutes after attending to recovery room are measured. Epinephrine and blood glucose level are measured via blood test before starting the operation (after anesthesia induction) and after finish running suturing (before reverse).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190222042806N1**
Registration date: **2019-09-25, 1398/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-25, 1398/07/03**
Update count: **0**

Registration date

2019-09-25, 1398/07/03

Registrant information

Name

Elham Sheyda Golbad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Propofol and Isoflurane on Hemodynamics Parameters and Stress Response Hormones during Laparoscopic Cholecystectomy

Public title

The Effect of Propofol and Isoflurane on Hemodynamics Parameters and Stress Response Hormones during Laparoscopic Cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with symptomatic gallstone disease Patients with acute cholecystitis Patients without inside or outside biliary tract dilatation American Society of Anesthesiologists (ASA) classification I , II

Exclusion criteria:

Obesity patients with class II or III (BMI>35) Patients with chronic liver disease, diabetes, renal failure, endocrine problems, rheumatoid arthritis, cardiovascular disease or malignancy Patients receiving drugs with known effects on sympathetic response or hormone secretion such as Beta-blockers Patients receiving benzodiazepines Pregnant or lactating mothers

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly divided into two groups based on simple randomization method using random digits table. In this method, a collection of non-template numbers is randomly generated and arranged as a table. Even numbers for the intervention group (1) and the odd numbers for the intervention group (2) are considered. According to the number of patients, they are randomly assigned to one of the intervention groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Responsible for collecting data, data analyzer

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Research deputy, Ahvaz Jundishapur University Of Medical Sciences, Golestan Blvd.

City

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Province

Khouzestan

Postal code

6135715794

Approval date

2018-11-24, 1397/09/03

Ethics committee reference number

IR.AJUMS.REC.1397.631

Health conditions studied

1

Description of health condition studied

Gallstone disease

ICD-10 code

K82.9

ICD-10 code description

Disease of gallbladder, unspecified

Primary outcomes

1

Description

Mean arterial pressure (MAP(

Timepoint

Time of starting the operation, every 5 minutes during the time between start of surgery till the completion of the surgical operation and 20 minutes after attending to recovery room

Method of measurement

Gauge pressure

2

Description

Heart rate

Timepoint

Time of starting the operation, every 5 minutes during the time between start of surgery till the completion of the surgical operation and 20 minutes after attending to recovery room

Method of measurement

Electrocardiograph signal

3

Description
Epinephrine level
Timepoint
Before starting the operation (after anesthesia induction) and after finish running suturing (before reverse)
Method of measurement
Blood test

4

Description
Blood glucose
Timepoint
Before starting the operation (after anesthesia induction) and after finish running suturing (before reverse)
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (1): Intravenous injection of propofol 50-150 µg/kg/min is performed.
Category
Treatment - Drugs

2

Description
Intervention group (2): Isoflurane with mac: 1.28% atm/mmhg is vaporized and patients inhale.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital, Ahvaz Jundishapur University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
PAIN-9710
Grant code / Reference number
330094424
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Elham Shayda Golbad
Position
Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available