

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 61 3222 0168

##### Email address

sheyda.e@ajums.ac.ir

##### 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

Ahvaz

##### Province

Khuzestan

##### 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

**Full name of responsible person**

Ali Ghomeishi

**Street address**

Razi Hospital, Palestin Ave.

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**Phone**

+98 61 3333 5935

**Email**

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badavi, PhD

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Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

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info@ajums.ac.ir

**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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Elham Shayda Golbad

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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Medical doctor

**Other areas of specialty/work**

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**Email**

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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