

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The comparison effect of dexmedetomidine and propofol on hemodynamics parameters and stress response hormones during laparoscopic cholecystectomy in patients referred to Razi Hospital in 2019-2020

#### Protocol summary

##### Study aim

The Comparison effect of Dexmedetomidine and propofol on hemodynamics parameters and stress response hormones during laparoscopic cholecystectomy

##### Design

Clinical trial contain control group receiving Propofol, with parallel group receiving Dexmedetomidine, triple blinded, randomized, phase 2-3 on 70 patients, for randomization will use simple method according odd or even case file number.

##### Settings and conduct

The statistical population of this project consists of 70 patients referred to Ahvaz Jundishapur Hospital. To induce anesthesia in both groups, a combination of midazolam (0.05 mg / kg), fentanyl (2 µg / kg), thiopental sodium (4 mg / kg), and atracurium (0.5 Mg / kg) will be used intravenously. Patients do not know which group they are.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include patients who have between 20 to 60 age years old that specifically have symptoms of gallstones or acute cholecystitis without stone. Those patients who have not consent of participation or type of surgery changed during operation will be excluded

##### Intervention groups

In the propofol group, propofol (75 µg / kg/min) and atracurium (0.1 mg/kg) will be used intravenously and alternately every 20 minutes as a relaxant to maintain anesthesia. The dexmedetomidine group will be given dexmedetomidine immediately after induction at a bolus dose of 1 µg / kg, followed by an infusion of 0.5 µg / kg until the end of surgery. Atracurium (0.1 mg/kg) will be used intravenously and alternately every 20 minutes as a relaxant.

##### Main outcome variables

Plasma level Epinephrine Plasma level Norepinephrine

Plasma level Cortisol

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200225046610N1**

Registration date: **2020-12-15, 1399/09/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-15, 1399/09/25**

Update count: **0**

##### Registration date

2020-12-15, 1399/09/25

##### Registrant information

##### Name

Farzad Khalvati Fahliani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3333 7446

##### Email address

khalvatifarzad@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-20, 1399/01/01

##### Expected recruitment end date

2021-03-21, 1400/01/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The comparison effect of dexmedetomidine and propofol on hemodynamics parameters and stress response hormones during laparoscopic cholecystectomy in patients referred to Razi Hospital in 2019-2020

**Public title**

The comparison effect of dexmedetomidine and propofol during laparoscopic cholecystectomy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patients between 20 to 60 age years old The candidate patients for laparoscopic cholecystectomy

**Exclusion criteria:**

The patients have class II or III obesity Chronic liver disease Diabetes Kidney disease Endocrine problems Romatoid disease The cardiovascular disease patients which use a beta-blocker drug that affects sympathies response and hormonal secretion and finally The person uses benzo diazepines are excluded from this study

**Age**

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

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Due to two group of study, randomization is simple method. According being to odd or even of last number of case file number, Patient will divided to one of group

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

All participants in this study, which include two intervention groups one and two, will be given the necessary drug information and will participate in the project with full knowledge, but do not know which group they are in. The main researcher of the project define A and B group that second physician (Anesthetist resident) and statistician dose not any knowledge type of drug in grouping.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz jundishapour University of Medical Sciences

**Street address**

Ahvaz Jundishapur University of Medical Sciences, Golestan St. , Ahvaz , Iran.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Approval date**

2020-01-18, 1398/10/28

**Ethics committee reference number**

IR.AJUMS.REC.1398.778

**Health conditions studied****1****Description of health condition studied**

laparoscopic cholecystectomy patients

**ICD-10 code**

K80.40

**ICD-10 code description**

Calculus of bile duct with cholecystitis, unspecified, without obstruction

**Primary outcomes****1****Description**

Heart rate

**Timepoint**

At the beginning and end of the study

**Method of measurement**

Anesthesia Monitoring system

**2****Description**

Mean atrial blood pressure (MAP)

**Timepoint**

At the beginning and end of the study

**Method of measurement**

Anesthesia Monitoring system

**3****Description**

Duration of anesthesia

## Timepoint

At the beginning and end of the study

## Method of measurement

Extraction of patient anesthesia sheet

## 4

### Description

Plasma level of blood sugar

### Timepoint

At the beginning and end of the study

### Method of measurement

Lab by specto-photometry method

## 5

### Description

level of stress hormone (epinephrine, nor-epinephrine, cortisol)

### Timepoint

At the beginning and end of the study

### Method of measurement

Lab by ELISA method

## Secondary outcomes

## 1

### Description

Post operative nausea and vomiting (PONV)

### Timepoint

After release of recovery room each 6 Hr

### Method of measurement

Sensation of nausea and vomiting by Visual Analogue Scale

## Intervention groups

## 1

### Description

intervention group 1: To induce anesthesia in both groups, a combination of midazolam (Caspian CO.)(0.05 mg / kg), fentanyl (Caspian CO.) (2 µg / kg), thiopental sodium (VUAB pharma CO.) (4 mg / kg), and atracurium (Caspian CO.) (0.5 Mg / kg) will be used intravenously. The propofol group, propofol (Fresenius CO.) (75 µg / kg/min) and atracurium (Caspian CO.) (0.1 mg/kg) will be used intravenously and alternately every 20 minutes as a relaxant to maintain anesthesia.

### Category

Treatment - Drugs

## 2

### Description

intervention group 2: Induction of anesthesia will be the same as the previous group. Dexmedetomidine will be given immediately after induction with dexmedetomidine (Exir CO) at a bolus dose of 1 µg /kg. for maintenance of Anesthesia propofol (Fresenius CO.) (75 µg/kg/min) and atracurium (Caspian CO.) (0.1 mg/kg) will be used

intravenously and alternately every 20 minutes as a relaxant to maintain anesthesia.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Farzad Khalvati

#### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan St. , Ahvaz , Iran.

#### City

Ahvaz

#### Province

Khuzestan

#### Postal code

6135715794

#### Phone

+98 61 6475 9841

#### Email

info@ajums.ac.ir

#### Web page address

<https://en.ajums.ac.ir/en-US/en.ajums.ac/33221/page/Home>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Ahvaz University of Medical Sciences

#### Full name of responsible person

Mohammad Badavi

#### Street address

Ahvaz Jundishapur University of Medical Sciences (AJUMS) , Golestan Blvd, Ahvaz

#### City

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#### Province

Khuzestan

#### Postal code

6135715794

#### Phone

+98 61 6475 9841

#### Email

info@ajums.ac.ir

#### Grant name

#### Grant code / Reference number

#### 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

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 6475 9841

**Email**

ghomeishi-a@ajums.ac.ir

**Person responsible for general inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Farzad Khalvati

**Position**

Non-faculty specialist physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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khalvatifarzad@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ali Ghomeishi

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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**City**

ahvaz

**Province****Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Farzad Khalvati

**Position**

Non-faculty specialist physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Email**

khalvatifarzad@gmail.com

**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