

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 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 Fahlani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3333 7446

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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

Khouzestan

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 spectro-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

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

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

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

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

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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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ahvaz

Province**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