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 dexmedomethidine immediately after induction at a bolus dose of 1 1 / kg, followed by an infusion of 0.5 µ / 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

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Farzad Khalvati Fahliani
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Iran (Islamic Republic of)
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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.
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Ahvaz
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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 specto-photometery 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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Position
Non-faculty specialist physician
Latest degree
Medical doctor
Other areas of specialty/work
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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