

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the Effect of Dexmedetomidine on hemodynamics of Patients and the Mean Rate of Isoflurane Consumption in Laparoscopic Cholecystectomy surgery

Protocol summary

Study aim

The effect of dexmedetomidine on hemodynamics of patients and the average amount of isoflurane consumed by patients during laparoscopic cholecystectomy

Design

The trial should have a control group, with parallel, double-blind, randomized, phase 3 groups performed on 80 patients. A table of random numbers is used for randomization.

Settings and conduct

This study will be performed on patients undergoing laparoscopic cholecystectomy referred to Valiasr Hospital in Arak as a randomized clinical trial with a control group. This study is a two-way blind and patients will be blind, clinical caregiver and outcome assessor compared to the study groups and blinding will be done using placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for laparoscopic cholecystectomy, age 18 to 65 years. Conditions of non-entry: do not undergo general anesthesia, cardiopulmonary disease, operation time more than 120 minutes

Intervention groups

In the dexmedetomidine group, for patients, 1 µg / kg of dexmedetomidine is placed in the form of a bolus, the volume of which has reached 20cc by normal saline, during induction of anesthesia on a syringe pump. They will then receive an infusion of 0.4 micrograms per kilogram per hour of dexmedetomidine during anesthesia. In the placebo group, 20cc of normal saline is placed on the syringe pump during induction and injected for patients. We will also put the equivalent of 50cc of normal saline, which is equal to the volume of dexmedetomidine used during anesthesia in the dexmedetomidine group, on the infusion pump.

Main outcome variables

Mean isoflurane consumption, mean systolic pressure,

pulse rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210508051221N1**

Registration date: **2021-05-16, 1400/02/26**

Registration timing: **prospective**

Last update: **2021-05-16, 1400/02/26**

Update count: **0**

Registration date

2021-05-16, 1400/02/26

Registrant information

Name

Hesam Rezaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 2222 2003

Email address

hesam.rezaei72@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Dexmedetomidine on hemodynamics of Patients and the Mean Rate of Isoflurane Consumption in Laparoscopic Cholecystectomy surgery

Public title

The effect of dexmedetomidine on hemodynamics of cholecystectomy patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate patients for laparoscopic cholecystectomy Age 18 to 65 years

Exclusion criteria:

Patients who do not undergo general anesthesia People with cardiopulmonary disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study will be done using the random number table method. In this way, The main performer randomly selects one of the numbers in the table by determining the direction of movement and moves in the selected direction in order. Then, based on the numbers obtained, odd numbers will be assigned to group A and even numbers will be assigned to group B.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blindness in this study will be double blind. In this way, patients are not aware of the type of drug used and the study groups, and only the main performer is aware of the type of intervention and drugs used and prepares the drugs with labels A and B. Also, the clinical caregiver and outcome assessor are not aware of the study groups and recognize the groups based on the letters A and B.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2020-11-15, 1399/08/25

Ethics committee reference number

IR.ARAKMU.REC.1399.240

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

Cholecystitis

ICD-10 code

K80.0

ICD-10 code description

Calculus of gallbladder with acute cholecystitis

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

Hemodynamics of patients

Timepoint

15, 30, 45, 60 and 90 minutes after the start of surgery

Method of measurement

Based on pulse rate and mean systolic pressure

Secondary outcomes**1****Description**

The amount of isoflurane consumed

Timepoint

From the beginning to the end of surgery

Method of measurement

check list

Intervention groups

1

Description

Intervention group: After induction of anesthesia, the mentioned patients are intubated and placed under a ventilator. For all the mentioned patients, isoflurane anesthesia will be used 1-2% per minute and then the surgeon will be allowed to start surgery and cholecystectomy. In the dexmedetomidine group, for patients, 1 µg / kg of dexmedetomidine (Imagen-Iran) is placed in the form of a bolus, the volume of which has reached 20cc by normal saline. They will receive dexmedetomidine as an infusion.

Category

Treatment - Drugs

2

Description

Control group: After induction of anesthesia, the mentioned patients are intubated and placed under a ventilator. For all the mentioned patients, isoflurane anesthesia will be used 1-2% per minute and then the surgeon will be allowed to start surgery and cholecystectomy. In the placebo group, 20 cc of normal saline is placed on the syringe pump during induction and injected for patients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Hesam Rezaee

Street address

Valiasr Hospital

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

pr_valieasr@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3639

Email

research@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Hesam Rezaee

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3639

Email

research@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hesam Rezaee

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3639

Email

research@arakmu.ac.ir

Payambar-e-azam Complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3639

Email

research@arakmu.ac.ir

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

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

Arak University of Medical Sciences

Full name of responsible person

Hesam Rezaee

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address