

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of hemodynamic and antiemetic effects of midazolam combination with three drugs , ephedrine, dexamethasone and dexmedetomidine in patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim

Comparison of hemodynamic and antiemetic effects of midazolam combination with three drugs , ephedrine, dexamethasone and dexmedetomidine in patients undergoing laparoscopic cholecystectomy

Design

The study of the two-course clinical trial of 96 patients was randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Candidates for laparoscopic cholecystectomy in Valiasr Hospital in Arak are divided into 3 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for laparoscopic cholecystectomy, ASA class 1 and 2 , no history of mental illness and psychosis, no Parkinson's disease, motion sickness or history of chemotherapy, patients under general anesthesia, duration of surgery 60 to 150 minutes, lack of sensitivity to the drugs used, no hypertension and no vascular problems Exclusion criteria: patients without conscious consent, death of the patient

Intervention groups

Intervention group 1: 0.5 mg / kg ephedrine will be prescribed. (Made by Biotica Pharmaceutical Company)
Intervention group 2: 0.05 mg / kg dexamethasone will be prescribed. (Caspian Tamin Company, Rasht - Iran)
Intervention group 3: 1 mcg / kg dexmedetomidin will be prescribed. (Exir - Iran)

Main outcome variables

Nausea, vomiting, sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N151**

Registration date: **2021-02-21, 1399/12/03**

Registration timing: **prospective**

Last update: **2021-02-21, 1399/12/03**

Update count: **0**

Registration date

2021-02-21, 1399/12/03

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic and antiemetic effects of midazolam combination with three drugs , ephedrine, dexamethasone and dexmedetomidine in patients undergoing laparoscopic cholecystectomy

Public title

Comparison of hemodynamic and antiemetic effects of midazolam combination with three drugs , ephedrine, dexamethasone and dexmedetomidine in patients undergoing laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate patients for laparoscopic cholecystectomy ASA class 1 and 2 No history of mental illness and psychosis No Parkinson's disease, motion sickness or history of chemotherapy Patients under general anesthesia Duration of surgery 60 to 150 minutes Lack of sensitivity to the drugs used No hypertension and no vascular problems

Exclusion criteria:

Patients without conscious consent Death of the patient

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random allocation with envelopes in 2 groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is clinical trial.Outcome evaluator and analyzer and participant are blind (double blind).Outcome evaluator and analyzer and participant don't aware from grouping.

Placebo

Not 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

Ethics committee, Research center, Payambar Azam complex, Basij square ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-01-24, 1399/11/05

Ethics committee reference number

IR.ARAKMU.REC.1399.311

Health conditions studied

1

Description of health condition studied

cholecystectomy

ICD-10 code

K91.86

ICD-10 code description

Retained cholelithiasis following cholecystectomy

Primary outcomes

1

Description

Incidence of nausea

Timepoint

Recovery and 2, 4, 6, 12 and 24 hours after surgery

Method of measurement

Observation

2

Description

Vomiting

Timepoint

Up to 24 hours after surgery

Method of measurement

Score 0 to 4

3

Description

Severe nausea
Timepoint
Up to 24 hours after surgery
Method of measurement
Visual analog scale

4

Description
Sedation
Timepoint
In recovery and 1, 2 and 4 hours after surgery
Method of measurement
Ramsay score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: 0.5 mg / kg ephedrine will be prescribed. (Made by Biotica Pharmaceutical Company)
Category
Treatment - Drugs

2

Description
Intervention group 2: 0.05 mg / kg dexamethasone will be prescribed. (Caspian Tamin Company, Rasht - Iran)
Category
Treatment - Drugs

3

Description
Intervention group 3: 1 mcg / kg dexmedetomidin will be prescribed. (Exir - Iran)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Hesamodin Modir
Street address
Valiasr hospital, Valiasr squire
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3848176941
Phone

+98 86 3222 2003
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modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza Kamali
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
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alikalaliir@yahoo.com
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
Dr Hesamedin Modir
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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A Level or less

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Fax
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Email
Dorsadalaiei@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Hesamodin Modir

What processes are involved for a request to access data/document

Correspondence should be made with professors and universities.

Comments