

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

A comparative study of the effect of adding intravenous dexmedetomidine or intraperitoneal dexmedetomidine to intraperitoneal bupivacaine on pain after laparoscopic cholecystectomy.

Protocol summary

Study aim

Comparison of the effect of intraperitoneal dexmedetomidine or intravenous dexmedetomidine in combination with intraperitoneal bupivacaine on pain after laparoscopic cholecystectomy.

Design

Randomised, with a control group, parallel group trial with blinded outcome assessment, randomisation was done with random allocation software.

Settings and conduct

This study is a triple-blinded randomized clinical trial on 90 patients who are candidates for laparoscopic cholecystectomy in Al-zahra operating room at Isfahan city. After the approval of the ethics committee of the university and obtaining the consent of the patients, the patients will be randomly assigned into 3 groups, in each group the intended intervention is applied and the patient's data and symptoms are recorded. In case of any change in anesthesia method and change of operation to open type, patients will be excluded from the study. The patients, the researcher who records the patient's symptoms, and the analysts who analyze the collected data don't know the type of intervention applied in each group and therefore they are all blind.

Participants/Inclusion and exclusion criteria

• Inclusion criteria: candidate patients for laparoscopic cholecystectomy surgery, age between 18-65 years old, ASA I & II. • Exclusion criteria: patients with a history of allergy to the drugs used in the study, patients with inability to express the intensity of pain based on the VAS criteria.

Intervention groups

Group 1: 20 ml bupivacaine 0.25% with dexmedetomidine at a dose of 1 µg/kg intraperitoneally, group 2: 20 ml bupivacaine 0.25% intraperitoneally and dexmedetomidine at a dose of 1 µg/kg iv. control group 22cc N/S intraperitoneal

Main outcome variables

vas pain score, dosage of additional analgesic, frequency of nausea & vomiting, pulse rate, O2 saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N53**

Registration date: **2023-07-08, 1402/04/17**

Registration timing: **prospective**

Last update: **2023-07-08, 1402/04/17**

Update count: **0**

Registration date

2023-07-08, 1402/04/17

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of adding intravenous dexmedetomidine or intraperitoneal dexmedetomidine to intraperitoneal bupivacaine on pain after laparoscopic cholecystectomy.

Public title
The effect of intravenous and intraperitoneal dexmedetomidine in combination with intraperitoneal bupivacaine on postoperative pain

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for laparoscopic cholecystectomy surgery
ASA I & II(American society of anesthesiologist) Informed Consent to participate in the study
Exclusion criteria:
Patients with a history of allergy to the drugs used in the study (dexmedetomidine and bupivacaine) Patients with psychological problems Patients with a history of drug addiction Patients with the inability to express the intensity of pain based on the vas criterion

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by the simple method , the samples are randomly placed in three intervention groups 1 and 2 and control by random allocation software. Sampling continues until the samples in all three groups reach the set limit.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This study is a triple blind clinical trial,in this way, the patient is included in the study but does not know the type of intervention applied and is blind, the person who records the patient's symptoms is also different from the person who injects the drug And without knowing the type of drug, only records the patient's symptoms during the study and therefore is kept blind. The analysts who analyze the data collected during the study also do not know the type of intervention applied in each group and

are blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committees of School of Medicine- Isfahan university of Medical Sciences
Street address
Hezar jerib
City
Isfahan
Province
Isfahan
Postal code
8174673461
Approval date
2023-04-24, 1402/02/04
Ethics committee reference number
IR.MUI.MED.REC.1402.051

Health conditions studied

1

Description of health condition studied
postoperative pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
the severity of postoperative pain
Timepoint
In base time9before intervention), every 15 minutes in recovery,in 2, 4, 6, 12, 24 hours after surgery.
Method of measurement
Visual Analogue Scale(0-10)

Secondary outcomes

1

Description
Mean arterial pressure
Timepoint
In base time(before intervention), every 30 minutes

during operation and then in recovery

Method of measurement

barometer

2

Description

Heart Rate

Timepoint

In base time(before intervention), every 30 minutes during operation and then in recovery

Method of measurement

ECG

3

Description

Arterial blood oxygen saturation

Timepoint

In base time(before intervention), every 30 minutes during operation and then in recovery

Method of measurement

pulse oximeter

4

Description

complication(nausea and vomiting)

Timepoint

In base time(before intervention), every 30 minutes during operation and then in recovery

Method of measurement

asking

Intervention groups

1

Description

Intervention group1: In this group of patients who dont eat anything for at least 8 hours before the operation, 20 ml of bupivacaine 0.25% with 1 µg/kg of dexmedetomidine was injected intraperitoneally in the bedside of the gallbladder after the last clamp and just before the removal of the trocar of laparoscope.

Category

Prevention

2

Description

Intervention group 2: In this group of patients who dont eat anything for at least 8 hours before the operation, at the end of the operation and after the last clamp and just before the removal of trocar of laparoscope , 20 ml bupivacaine 0.25% intraperitoneally and 1 microgram/kg dexmedetomidine are injected into the patients.

Category

Prevention

3

Description

Control group: In this group, 22 cc of normal saline is injected intraperitoneally at the end of the operation to patients who have not eaten anything for at least 8 hours before the operation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Behzad nazemoroaya

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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

Esfahan 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
Esfahan University of Medical Sciences
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Position
Medical student
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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