Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparison study of the preemptive of the two dose of dexmedetomidine (bolus and infusion) on post operative pain, nausea and vomiting for laparoscopic cholecystectomy

Protocol summary

Study aim
Comparative determination of the preemptive of the two dose of dexmedetomidine (bolus and infusion) on post operative pain, nausea and vomiting for laparoscopic cholecystectomy

Design
Clinical trial with control group, with parallel groups, double blind, randomized on 90 patients, Randomized Allocation software was used for randomization

Settings and conduct
This is a double blind study in which the patient and the interventional physician are blind, and it is collected from selected hospitals under the supervision of Isfahan University of Medical Sciences. We have a study group to which the bolus dose and infusion of dexmedetomidine are administered before surgery and the amount of pain, nausea and vomiting after surgery is compared.

Participants/Inclusion and exclusion criteria
Entry requirements Candidate patients for surgery with an age range of 18 to 65 years and ASA 1,2 Non-entry requirements Patients with BMI above 30, drug addiction, chronic use of painkillers and sleeping pills, and drug allergy

Intervention groups
Group A received intravenous dexmedetomidine at the rate of 1 microgram per kilogram of body weight as a bolus dose 20 minutes before induction of anesthesia, and then 0.5 microgram per kilogram of body weight was given as an infusion for 15 minutes. Group B received intravenous dexmedetomidine at the rate of 1 microgram per kilogram of body weight as a bolus dose 20 minutes before induction of anesthesia, and then 0.7 microgram per kilogram of body weight was given as an infusion for 15 minutes. Group C uses normal saline instead of dexmedetomidine.

Main outcome variables
Pain, nausea and vomiting after surgery

General information

Reason for update

Acronym
پره امپتیو، دکسمدتومیدین، درد و تهوع و استفراغ، کولهسیستکتومی لاپاراسکوپی

IRCT registration information
IRCT registration number: **IRCT20101211005362N31**
Registration date: **2022-11-07, 1401/08/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-07, 1401/08/16**
Update count: **0**

Registration date
2022-11-07, 1401/08/16

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2023-03-16, 1401/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison study of the preemptive of the two dose of dexmedetomidine (bolus and infusion) on post operative pain, nausea and vomiting for laparoscopic cholecystectomy

Public title
Comparison study of the pre emptive of the two dose of dexmedetomidine (bolus and infusion) on post operative pain, nausea and vomiting for laparoscopic cholecystectomy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
patient candidate to be operated laparoscopic cholecystectomy one and two ASA age between 18 - 65 year Patient consent to participate in the study
Exclusion criteria:
Drug addiction History of dexmedetomidine allergy People with a BMI above 30 Use of sleeping pills and analgesics chronically
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method is based on simple random method that means, all the samples which are eligible to participate in the study will be included in the study until the sample size is completed. Then, the patients who entered the study will be randomly divided into three groups using the Randomize Allocation software. Random Allocation software (version 2.0) will be used. Sampling will be done by the method of 3 permutation blocks. In this way, we will have 15 blocks of 6 and each block contains 6 letters from A, C and B, including AABBCC-ABCABC-BCBACA-BABACC and etc. (three groups of 30). Each patient is given a card at random. The cards are in sealed envelopes and the anesthesiologist takes the envelopes in order and delivers them to the patients. People with card A receive intravenous dexmedetomidine at a rate of 1 µg per kg of body weight as a bolus dose 20 minutes before induction of anesthesia and then receive 0.5 µg per kg of body weight as an infusion over 15 minutes. People who have card B receive intravenous dexmedetomidine at the rate of 1 µg per kg of body weight as a bolus dose 20 minutes before induction of anesthesia and then 0.7 µg per kg of body weight as an infusion for 15 minutes. People who have card C routinely faint. The person who collects the data does not know whether the data is related to group A, group B or group C.
Blinding (investigator's opinion)
Double blinded
Blinding description
The method of blinding in this study is that the drugs are used by coding method and with syringes of equal volume for all patients. Also, the first anesthesiologist injects the drug based on simple random method then data collection is done by the second anesthesiologist. In addition the patients and the interventionist doctor do not know about studied groups, during the research project.
Placebo
Used
Assignment
Parallel
Other design features
In a clinical trial study, we should compare the administration of two bolus doses and infusion of dexmedetomidine on pain, nausea and vomiting in patients undergoing laparoscopic cholecystectomy.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan university of medical science
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81746-73461
Approval date
2022-03-26, 1401/01/06
Ethics committee reference number
IR.MUI.MED.REC.1401.007

Health conditions studied

1

Description of health condition studied
Pain, nausea and vomiting
ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Comparison of the effect of different doses of dexmedetomidine on amount of pain.
Timepoint
The first hour of recovery every 15 minutes, then 6 hours later, every two hours, and then 12, 24 and 48 hours later is evaluated.
Method of measurement
Pain intensity based on VAS scoring system and severity of nausea and vomiting using PONV system

2

Description
Comparing the effect of different doses of dexmedetomidine on nausea severity
Timepoint
The first hour of recovery every 15 minutes, then 6 hours later every two hours, and then 12, 24 and 48 hours later is evaluated.
Method of measurement
The severity of nausea is measured using the PONV system

3

Description
Comparing the effect of different doses of dexmedetomidine on vomiting severity
Timepoint
The first hour of recovery every 15 minutes, then 6 hours later, every two hours, and then 12, 24 and 48 hours later is evaluated.
Method of measurement
The severity of vomiting is measured using the PONV system

Secondary outcomes

1

Description
blood pressure
Timepoint
The first hour of recovery is evaluated every 15 minutes, then 6 hours later, every two hours, and then 12, 24 and 48 hours later
Method of measurement
Blood pressure is measured using a sphygmomanometer

2

Description
heart beat
Timepoint
The first hour of recovery is evaluated every 15 minutes, then every two hours after 6 hours, and then 12, 24, and 48 hours later.
Method of measurement
Heart rate is measured using a pulse oximeter

3

Description
Blood oxygen level
Timepoint
The first hour of recovery is evaluated every 15 minutes, then every two hours after 6 hours, and then 12, 24, and 48 hours later.
Method of measurement
Blood oxygen is measured using a pulse oximeter

4

Description
amount of drugs
Timepoint
The first hour of recovery is evaluated every 15 minutes, then every two hours after 6 hours, and then 12, 24, and 48 hours later.
Method of measurement
Using the volume in cc used

Intervention groups

1

Description
Intervention group: Intravenous dexmedetomidine at a dose of 1 microgram per kilogram of body weight is given as a bolus dose 20 minutes before induction of anesthesia and then 0.5 micrograms per kilogram of body weight for infusion for 15 minutes.
Category
Treatment - Drugs

2

Description
Intervention group: Intravenous dexmedetomidine at a dose of 1 microgram per kilogram of body weight is given as a bolus dose 20 minutes before induction of anesthesia and then 0.7 micrograms per kilogram of body weight is infused for 15 minutes.
Category
Treatment - Drugs

3

Description
Control group: instead of dexmedetomidine, we use 10 cc of normal saline before induction of anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Selected hospitals under the supervision of Isfahan University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Full name of responsible person
Mohammadreza Safavi

Position
Associate Professor of Anesthesia

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available