Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of preemptive administration of two doses of dexmedetomidine in the prevention of chills, pain, nausea and vomiting after laparoscopic gallbladder surgery

Protocol summary

Study aim

Determining and comparing the effect of intravenous injection of dexmedetomidine with two doses on chills after elective surgery in patients under general anesthesia

Design

A non-randomized, triple-blinding clinical trial, with the parallel groups, Phase 3 on 75 patients

Settings and conduct

In this non-randomized triple-blind clinical trial, 75 eligible patients referred to Al-Zahra and Kashani Hospitals in Isfahan will be included in the study and divided into three groups. Patients in the first group dexmedetomidine at a dose of 0.3 ug/kg, and in the second group dexmedetomidine at a dose of 0.5 ug/kg, and in the control group placebo will be injected. The intervention will be performed in such a way that the patient, the researcher, and the statistical analyst will have no knowledge of the type of intervention and the triple-blind conditions will be established. Then the severity of chills and hemodynamic parameters of the patients will be evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients who are candidates for laparoscopic cholecystectomy surgery, American Society of Anesthesiologists classification equal to I and II, age range 18-65 years, and consent to participate in the study. Exclusion criteria include the history of monoamine oxidase inhibitor (MAOI), tricyclic antidepressant (TCA), vasoactive, analgesic, and opioids before surgery.

Intervention groups

Intervention group 1: For patients in this group, dexmedetomidine at a dose of 0.3 ug/kg is injected as a bolus over ten minutes. Second intervention group: For patients in this group, dexmedetomidine at a dose of 0.5 ug/kg is injected as a bolus over ten minutes. Control group: For patients in this normal group, the same volume of drugs from the previous two groups is injected intravenously as a bolus for ten minutes.

Main outcome variables

Chills; Hemodynamic parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N53**
Registration date: **2022-05-13, 1401/02/23**
Registration timing: **prospective**

Last update: **2022-05-13, 1401/02/23**
Update count: **0**

Registration date

2022-05-13, 1401/02/23

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of preemptive administration of two doses of dexmedetomidine in the prevention of chills, pain, nausea and vomiting after laparoscopic gallbladder surgery

Public title
Evaluation of the effect of administration of two doses of dexmedetomidine in the prevention of chills, pain, nausea and vomiting after gallbladder surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients candidates for laparoscopic cholecystectomy American Anesthesiologists Association (ASA) Classification I and II Age category 65-18 years Satisfaction to participate in the study
Exclusion criteria:
History of monoamine oxidase inhibitor (MAOI), tricyclic antidepressant (TCA), vasoactive, analgesic, opioid before surgery
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to achieve the triple-blind study, different doses of dexmedetomidine and placebo will be prepared daily by the anesthesiologist (without the researcher's awareness) and placed in the bag and will be labeled A, B, C and will be provided daily to the researcher. Therefore, the patient, the Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2021-12-26, 1400/10/05
Ethics committee reference number
IR.MUI.MED.REC.1400.716

Health conditions studied

1

Description of health condition studied
Elective surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Chills
Timepoint
Every 15 minutes in recovery and every 6 hours in the ward up to 24 hours after surgery
Method of measurement
Observention

Secondary outcomes

1

Description
Systolic blood pressure
Timepoint
At the start of surgery, every 30 minutes during surgery, every 30 minutes in recovery, and every 6 hours in the ward for up to 24 hours after surgery.

Method of measurement
Monitoring device

2

Description
Diastolic blood pressure
Timepoint
At the start of surgery, every 30 minutes during surgery, every 30 minutes in recovery, and every 6 hours in the ward for up to 24 hours after surgery.
Method of measurement
Monitoring device

3

Description
Hear rate
Timepoint
At the start of surgery, every 30 minutes during surgery, every 30 minutes in recovery, and every 6 hours in the ward for up to 24 hours after surgery.
Method of measurement
Monitoring device

Intervention groups

1

Description
Intervention group 1: For patients in this group, dexmedetomidine(Elixir Pharmaceutical Company) at a dose of 0.3 ug/kg is injected as a bolus over ten minutes.
Category
Treatment - Drugs

2

Description
Second intervention group: For patients in this group, dexmedetomidine(Elixir Pharmaceutical Company) at a dose of 0.5 ug/kg is injected as a bolus over ten minutes.
Category
Treatment - Drugs

3

Description
Control group: For patients in this group, normal saline of the same volume of drugs of the previous two groups is injected intravenously, as a bolus for ten minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Mohamadreza Safavi
Street address
Soffe Blvd, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
Mr_safsavi@med.mui.ac.ir

2

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Mohamadreza Safavi
Street address
Anesthesiology Department, Kashani Hospital, Kashani Street.
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Mr_safsavi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash Dastjerdi
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Isfahan 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
Mohamadreza Safavi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

Contact
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Email
dr.r.dehghanniri88@gmail.com

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 further 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