Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of the Dexmedetomidin effect on postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy

Protocol summary

Study aim

Determination of the effect of dexmedetomidine on postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy

Design

This double-blind clinical trial began with the approval of the University Ethics Committee. Fifty female patients aged 20-50 years who were candidates for cholecystectomy under general anesthesia were randomly divided into two equal groups using random allocation. The study was a double-blind study and the outcome assessor was unaware that the patient belonged to the intervention group or normal saline (control group).

Settings and conduct

Imam Khomeini Hospital started the operation and before cutting the skin to insert a laparoscope device in the study group dexmedetomidine, at a dose of 0.8 µg / kg in 100 cc of normal saline for ten minutes and in the control group 100 cc of serum N / S was infused under the same conditions .

Participants/Inclusion and exclusion criteria

50 patients 50-20 years old female candidates for cholecystectomy under general anesthesia Inclusion criteria included adult patients with physical condition I-II of the American Society of Anesthesiologists (ASA) undergoing laparoscopic cholecystectomy for acute and chronic cholecystitis Exclusion criteria included drug sensitivity in the study, receiving antiemetic drugs in the last 48 hours before surgery and body mass index above 35 kg / m2, surgery more than 2 hours, other concomitant surgery, complications during or after surgery and no Consent to participate in this study

Intervention groups

Dexmedetomidine study group Normal saline group

Main outcome variables

Nausea / vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170411033365N2**
Registration date: **2021-11-10, 1400/08/19**
Registration timing: **retrospective**

Last update: **2021-11-10, 1400/08/19**
Update count: **0**

Registration date

2021-11-10, 1400/08/19

Registrant information

Name
Alireza Mahoori
Name of organization / entity
Urmia University of Medical Sciences
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Iran (Islamic Republic of)
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+98 44 3346 8967
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mahouri.a@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-20, 1400/06/29

Actual recruitment start date

2021-06-23, 1400/04/02

Actual recruitment end date

2021-09-20, 1400/06/29

Trial completion date

2021-09-20, 1400/06/29

Scientific title
Assessment of the Dexmedetomidin effect on postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy

Public title
Assessment of the Dexmedetomidin effect on postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Adult Patients with Physical Status I-II of the American Society of Anesthesiologists (ASA) undergoing laparoscopic cholecystectomy for acute and chronic cholecystitis
Exclusion criteria:
Sensitivity to drugs in the study, receiving antiemetic drugs in the last 48 hours before surgery and body mass index above 35 kg / m2, surgery more than 2 hours, other concomitant surgery, complications during or after surgery and dissatisfaction with the company in this study

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly using computer numbers generated by Random allocation software in two groups

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and outcome assessors were unaware that the patient belonged to the intervention group or normal saline (control group). The outcome assessor was someone other than the person who had injected the drug and normal saline

Placebo
Used

Assignment
Parallel

Other design features
This double-blind clinical trial began with the approval of the University Ethics Committee. Conscious written consent was obtained from patients to participate in the study. Fifty patients aged 20-50 years old who were candidates for cholecystectomy under general anesthesia in two equal groups (25 patients in each group) in Imam Khomeini Hospital of Urmia affiliated to Urmia University of Medical Sciences were randomly generated using computer numbers. They were divided into two groups by Random allocation software.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
IR.UMSU.REC.1400.113
Street address
بلوار آیت ا..مدرس-خیابان ارشاد
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ارومیه
Province
West Azarbaijan
Postal code
5715789397

Approval date
2021-06-22, 1400/04/01

Ethics committee reference number
IR.UMSU.REC.1400.113

Health conditions studied

1

Description of health condition studied
Patients undergoing laparoscopic cholecystectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Nausea / vomiting

Timepoint
recovery

Method of measurement
A score of zero was equivalent to no nausea or vomiting and a score of 5 was equivalent to the highest severity of nausea or vomiting.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Dexmedetomidine group

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital in Urmia
Full name of responsible person
Dr. Ebrahim Hassani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
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Dr. Ebrahim Hassani
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Grant name
no
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
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Oroumia University of Medical Sciences
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Dr. Ebrahim Hassani
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Professor
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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
The data is confidential
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