

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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 / m<sup>2</sup>, 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3346 8967

##### Email address

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 / m<sup>2</sup>, 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

##### City

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

**Street address**

IMAM KHOMEINI UNIVERSTIY -ERSHAD AVE-  
MODARRES BLND-URMIA-IRAN

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715789397

**Phone**

+98 44 3198 8327

**Fax**

+98 44 3345 7277

**Email**

Mahuri.a@umsu.ac.ir

**Web page address**

<http://imam.umsu.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Ebrahim Hassani

**Street address**

IMAM KHOMEINI UNIVERSTIY -ERSHAD AVE-  
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**Email**

mahouri.a@umsu.ac.ir

**Web page address**

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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

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Ebrahim Hassani

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

IMAM KHOMEINI UNIVERSTIY -ERSHAD AVE-  
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**Email**

mahouri.a@umsu.ac.ir

**Web page address**

<http://imam.umsu.ac.ir>

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Mahouri

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Mahouri

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

IMAM KHOMEINI UNIVERSTIY -ERSHAD AVE-  
MODARRES BLND-URMIA-IRAN

**City**

urmia

**Province**

West Azarbaijan

**Postal code**

## 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