

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Assessment the effect of lidocaine intravenous infusion on postoperative pain in patients with laparoscopic cholecystectomy under general anesthesia

#### Protocol summary

##### Study aim

Determining the effect of intravenous lidocaine infusion on pain after laparoscopic cholecystectomy under general anesthesia

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 80 patients. Blanced Block Randomization was used for randomization.

##### Settings and conduct

Background is determining the effect of lidocaine on pain after cholecystectomy. Velayat hospita in Qazvin, Iran. Researcher, patient, surgeon, nurse, and data analyzer were blinded to the type of group the patient was in. 80 patients for laparoscopic cholecystectomy were divided into two groups of control and intervention by random allocation.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include 18-50 years old, ASA class I-II patients, candidates for elective laparoscopic cholecystectomy. Exclusion criteria include a history of seizures, allergies, hypertension, cardiovascular disease, the need for blood transfusions or their products, and the duration of surgery is more than 2.5 hours.

##### Intervention groups

For all patients for premedication midazolam 0.02 mg / kg and fentanyl 1.5 micrograms / kg and for induction of anesthesia propofol at a dose of 2 mg / kg injection and maintenance by intravenous infusion of propofol 100 micro / kg / min with oxygen 100 Percentage will be done. In the intervention group, after induction of general anesthesia at the beginning of surgery, intravenous infusion of lidocaine for 10 minutes at a dose of 1.5 mg / kg, and also during surgery until the end of intravenous infusion of lidocaine at a dose of 1.5 mg / min It will be done for all patients. In the control group, instead of lidocaine, intravenous infusion of normal

saline will be 0.9%.

##### Main outcome variables

Post operational pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201214049720N1**

Registration date: **2021-01-08, 1399/10/19**

Registration timing: **retrospective**

Last update: **2021-01-08, 1399/10/19**

Update count: **0**

##### Registration date

2021-01-08, 1399/10/19

##### Registrant information

##### Name

Minoo Sami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3333 3333

##### Email address

drmsami709@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

2019-09-23, 1398/07/01

**Actual recruitment end date**

2020-02-20, 1398/12/01

**Trial completion date**

2020-02-29, 1398/12/10

**Scientific title**

Assessment the effect of lidocaine intravenous infusion on postoperative pain in patients with laparoscopic cholecystectomy under general anesthesia

**Public title**

The effect of lidocaine on pain after gallbladder resection

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age range 18-150 years ASA class I-II patients Candidate for elective laparoscopic cholecystectomy

**Exclusion criteria:**

History of seizures Allergies Hypertension Cardiovascular disease Need for blood transfusion or its products Duration of surgery more than 2.5 hours

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **40**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the patient will not be aware of the type of study group in which he is placed, as well as the researcher, patient surgeon, patient care nurse in the operating room, recovery ward and post-surgery ward, as well as data analyzer will not be informed about patient grouping .

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

**Street address**

Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419759811

**Approval date**

2019-09-17, 1398/06/26

**Ethics committee reference number**

IR.QUMS.REC.1398.131

**Health conditions studied****1****Description of health condition studied**

cholecystitis

**ICD-10 code**

K80.01

**ICD-10 code description**

Calculus of gallbladder with acute cholecystitis with obstruction

**Primary outcomes****1****Description**

Post operational Pain

**Timepoint**

2, 4, 6 and 8 hours after surgery

**Method of measurement**

VAS

**Secondary outcomes****1****Description**

Amount of narcotic drug consumption

**Timepoint**

Post operation

**Method of measurement**

Patient Document

**Intervention groups****1****Description**

Intervention group: In the intervention group, after induction of general anesthesia at the beginning of surgery, intravenous infusion of lidocaine for 10 minutes at a dose of 1.5 mg / kg, and also during surgery until the end of intravenous infusion of lidocaine at a dose of 1.5 mg / min It will be done for all patients.

**Category**

Treatment - Drugs

**2****Description**

Control group: In the control group, instead of lidocaine, intravenous infusion of normal saline will be 0.9%.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Velayat Educational Hospital - Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Minoosami

**Street address**

Velayat Educational Hospital, Qazvin, Iran

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419759811

**Phone**

+98 28 3379 0620

**Email**

Ali32024@yahoo.com

**Web page address**

<http://hosvelayat.qums.ac.ir/portal/home>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Hesein Moeini

**Street address**

Qazvin University of Medical Sciences, Bahonar Blvd, Qazvin, Iran.

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419759811

**Phone**

+98 28 3336 9001

**Email**

Info@qums.ac.ir

**Web page address**

<http://www.qums.ac.ir/Portal/Home>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Qazvin University of Medical Sciences

**Proportion provided by this source**

5

**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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Minoosami

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

University of Medical Sciences, Bahonar Blvd, Qazvin, Iran.

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419759811

**Phone**

+98 28 3333 3333

**Fax****Email**

drmsami709@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Hesein Moeini

**Position**

Assistant Professor

**Latest degree**

Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Qazvin University of Medical Sciences, Bahonar Blvd,  
Qazvin, Iran.  
**City**  
Qazvin  
**Province**  
Qazvin  
**Postal code**  
3419759811  
**Phone**  
+98 28 3336 9001  
**Email**  
moeini200@gmail.com

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Minoo Sami  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
University of Medical Sciences, Bahonar Blvd, Qazvin,  
Iran.  
**City**  
Qazvin  
**Province**  
Qazvin  
**Postal code**

3419759811  
**Phone**  
+98 28 3333 3333  
**Fax**  
**Email**  
drmsami709@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Yes - There is a plan to make this available  
**Study Protocol**  
Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Yes - There is a plan to make this available  
**Title and more details about the data/document**  
Data on primary and secondary outcomes can be published.  
**When the data will become available and for how long**  
One year after the results are published  
**To whom data/document is available**  
Researchers and industry owners  
**Under which criteria data/document could be used**  
Use the results for further planning and research  
**From where data/document is obtainable**  
drmsami709@gmail.com  
**What processes are involved for a request to access data/document**  
drmsami709@gmail.com  
**Comments**