

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. Minoos Sami

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

Minoos 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

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