Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparative study of the effect of irrigation- suction system with 2% lidocaine during surgery on the reduction of postoperative pain in patients undergoing laparoscopic cholecystectomy in 1999

Protocol summary

Study aim
Evaluation of the effect of irrigation suction system with 2% lidocaine combination during surgery on reducing postoperative pain in patients undergoing laparoscopic cholecystectomy in 1399

Design
This study is a clinical trial. The study population consisted of 70 patients with cholecystitis who referred to treatment of their disease for cholecystectomy. The patient and the person evaluating the amount of pain and analyzing the data are unaware of the patient's treatment group and the study is a three-blind study.

Settings and conduct
The researcher goes to the hospital on different days and according to the patients' actions, from the list of hospitalized patients, first gives them the reason for doing this plan and other necessary explanations, and then, if the patients wish, interviews them. In terms of anonymity, participants will be reassured at all stages of the research, as well as when the data is published, and participants will be allowed to leave the study at any time

Participants/Inclusion and exclusion criteria
Inclusion criteria: - All patients with chronic cholecystitis are candidates for elective laparoscopic cholecystectomy The age of the patient should not be less than 20 and not more than 60 Exclusion criteria: - Taking drugs that can be effective on postoperative pain in patients - History of drug or alcohol use (now or in the past) Existence of acute gallbladder and acute cystitis Existence of severe inflammation and adhesions at the site of surgery so that open surgery is required Gallbladder rupture and bile leakage at the operation site Bleeding during surgery so that there is a possibility of peritoneal stimulation due to blood in the peritoneum

Intervention groups
Patients undergoing laparoscopic cholecystectomy

Main outcome variables
the patient's pain intensity and the number of days the patient stays in the hospital

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201006048950N1**
Registration date: **2020-12-08, 1399/09/18**
Registration timing: **prospective**

Last update: **2020-12-08, 1399/09/18**
Update count: **0**

Registration date
2020-12-08, 1399/09/18

Registrant information

Name
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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-21, 1399/12/03

Expected recruitment end date
2021-07-25, 1400/05/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of irrigation- suction system with 2% lidocaine during surgery on the reduction of postoperative pain in patients undergoing laparoscopic cholecystectomy in 1999

Public title

effect of irrigation- suction system on the reduction of postoperative pain in patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with chronic cholecystitis are candidates for elective laparoscopic cholecystectomy

Exclusion criteria:

Taking medications that can affect patients' postoperative pain

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after obtaining patient satisfaction, using random permutation block method, patients were randomly assigned to two groups of suction-irrigation with normal saline composition of 0.9% and suction irrigation with lidocaine combination of 2%. First, the name of each suction-irrigation method is an English letter such as A and B, and the randomization list will be a sequence of these two letters. Therefore, the person making the list is not aware of the method. In the random permutation block method, double blocks AB and BA are used. Randomization unit is a block. The lead researcher who conducts the study is only aware of the next patient's treatment and proceeds accordingly. Finally, 35 people are examined in each group, which includes a total of 70 patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is of the one-blind type. The patient is fully aware that he or she has participated in a study with two methods of suction irrigation and completes the informed consent form. But the patient does not know which irrigation suction method was used for him. Therefore, the patient is blinded.The lead researcher and her colleagues could not be blinded due to the implementation of irrigation suction methods

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Scienses, Dr Qarib Blvd., Basij Sq, Arak City

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2020-10-06, 1399/07/15

Ethics committee reference number

IR.ARAKMU.REC.1399.210

Health conditions studied

1

Description of health condition studied

Cholecystitis

ICD-10 code

K80.0

ICD-10 code description

cholecystitis

Primary outcomes

1

Description

Pain

Timepoint

0, 6, 12, 24 hours after surgery

Method of measurement

10 point pain ruler/ Select descriptive smileys

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Used 2%Lidocaine And 0.9%Sodium Chloride Serum : In the intervention group, the operation locale was Irrigated with 100 cc of 0.9% normal saline solution containing 2 mg / kg 2% lidocaine for 5-10 minutes and then the entire fluid was aspirated by the Suction-Irrigation Device as much as possible.
Category
Treatment - Drugs

2

Description
Control group: Just used 0.9%Sodium Chloride Serum
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-Asr (A.s) Education and Treatment Center
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Sponsors / Funding sources

1

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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available