

# 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

Mahboobeh Khosravani

##### Name of organization / entity

Arakuniversity of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3505

##### Email address

mahboobkhosravani@arakmu.ac.ir

##### 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 Sciences, 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

##### Full name of responsible person

Abolfazl Mohtarami

##### Street address

Vali-Asr (A.s) Education and Treatment Center, Vali-Asr Sq, Arak city

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Email

pr\_valieasr@arakmu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Amir-al-Momenin(A.S) Education and Treatment Center

##### Full name of responsible person

Abolfazl Mohtarami

##### Street address

Basij Sq, Dr Qarib Blvd

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3417 3601

#### Email

it-amiralmomenin@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Alireza Kamali

##### Street address

Basij Sq

##### City

Arak

##### Province

Markazi

##### Postal code

۶۹۴۱-۷-۳۸۴۸۱

##### Phone

+98 86 3417 3524

##### Email

amoozesh@arakmu.ac.ir

#### 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

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Abolfazl Mohtarami

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

General Surgery

##### Street address

Basij Sq

##### City

Arak

##### Province

Markazi

**Postal code**  
38481-7-6341  
**Phone**  
+98 86 3417 3520  
**Email**  
daneshkadeha@arakmu.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Mahboobeh Khosravani  
**Position**  
Faculty member  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Basij square,sardasht street.medical university of arak.faculth of nursing.  
**City**  
Markazi  
**Province**  
Markazi  
**Postal code**  
۶۹۴۱-۷-۳۸۴۸۱  
**Phone**  
+98 86 3417 3505  
**Fax**  
+98 86 3417 3524  
**Email**  
mahboobkhosravani@arakmu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**

Mahboobeh Khosravani  
**Position**  
Faculty member  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Basij square,sardasht street.medical university of arak.faculth of nursing.  
**City**  
Markazi  
**Province**  
Markazi  
**Postal code**  
۶۹۴۱-۷-۳۸۴۸۱  
**Phone**  
+98 86 3417 3505  
**Fax**  
+98 86 3417 3524  
**Email**  
mahboobkhosravani@arakmu.ac.ir

## 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