Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effectiveness of drain placement in laparoscopic cholecystectomy.

Protocol summary

Study aim
Assessment of the efficacy of drain placement in laparoscopic cholecystectomy.

Design
A randomized controlled trial, phase 2, will use permuted block stratified randomization for the allocation of 60 participants.

Settings and conduct
This study investigates the complications following laparoscopic cholecystectomy and the impact of drain usage in patients. The aim of this research is to enhance awareness regarding the potential outcomes of drain usage and its relation to patients' quality of life. The trial will be conducted at Imam Ali Hospital in Zahedan, where 60 patients meeting specific criteria will be randomly allocated into intervention and control groups using stratified block randomization. Demographic information and post-operative complications will be recorded in relevant forms and subsequently analyzed using SPSS software.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: All patients diagnosed with cholecystitis, whether elective or urgent, provided personal and informed consent. Exclusion Criteria Pregnant women, lack of personal consent from patients, any history of psychiatric disorders, age under 18 and over 65 years, having a BMI greater than 30, and having a BMI less than 19.

Intervention groups
The intervention group consists of patients who will have therapeutic drains placed during laparoscopic cholecystectomy. The aim of this procedure is to evaluate the impact of using drains on postoperative complications, including pain levels, nausea, vomiting, and the duration of recovery. Control Group The control group consists of patients who will not have any drains placed during laparoscopic cholecystectomy. The objective of this group is to compare postoperative complications with the intervention group.

Main outcome variables
Pain after drain placement Duration of the surgery Type of surgical procedure

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250616066203N1**
Registration date: **2025-07-04, 1404/04/13**
Registration timing: **prospective**

Last update: **2025-07-04, 1404/04/13**
Update count: **0**

Registration date
2025-07-04, 1404/04/13

Registrant information
Name
Sina Kiani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 54 3329 5770
Email address
dr.sina.kiani@zaums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-07-22, 1404/04/31
Expected recruitment end date
2026-02-20, 1404/12/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of drain placement in laparoscopic cholecystectomy.

Public title

General Title for Clinical Trial**Assessment of the Effectiveness of Drain Placement in Laparoscopic Cholecystectomy**

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Main inclusion criteria include patients who are candidates for drain placement during laparoscopic cholecystectomy.

Exclusion criteria:

Main exclusion criterion includes conversion of laparoscopic surgery to open surgery.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient allocation will be conducted using permuted block stratified randomization. Initially, eligible patients will be classified based on age and gender in the order of their arrival. They will then be allocated to the desired groups based on random selection of 4-member blocks (comprising two groups A and B, each with two repetitions). These blocks have been created using the statistical software R version 4..2.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

medical Sciences Campus Zahedan,Dr. Hesabi Square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2025-05-11, 1404/02/21

Ethics committee reference number

IR.ZAUMS.REC.1404.057

Health conditions studied

1

Description of health condition studied

Acute Cholecystitis

ICD-10 code

Acute chol

ICD-10 code description

K81.0

Primary outcomes

1

Description

Pain

Timepoint

12 hours and 24 hours after drainage placement

Method of measurement

Based on the VAS (Visual Analog Scale) criteria

2

Description

Nausea and vomiting

Timepoint

Based on the VAS (Visual Analog Scale) criteria

Method of measurement

Based on the visual criteria

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group consists of patients who will undergo cholecystectomy, and in this group, some patients will receive drains (for fluid drainage). The aim of this group is to assess the impact of the presence of drains on postoperative pain and associated complications, such as nausea and vomiting. Demographic information of these patients along with

the details of the surgery will be recorded in specific forms and subsequently subjected to statistical analysis.

Category

Treatment - Surgery

2

Description

Control Group:In this study, the control group will consist of patients who have undergone cholecystectomy without drain placement. These patients will be matched with the intervention group (with drain) in terms of age, sex, body mass index (BMI), and surgical status (elective or emergency). The same inclusion and exclusion criteria (e.g., age 18–65 years, no pregnancy, and no history of psychiatric disorders) will be applied to both groups.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Talib Hospital, Zahedan

Full name of responsible person

Sina

Street address

Persian Gulf Boulevard, Surgery Department,Ali Ibn Abi Talib Hospital,

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5564

Email

dr.sina.kiani@zaums.ac.ir

Web page address

https://alihos.zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Alireza Ansari Moghaddam

Street address

Vice Chancellor for Research and Technology, University of Zahedan,Medical Sciences Campus,Persian Gulf Boulevard

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3337 2117

Email

nfo@zaums.ac.ir

Web page address

https://research.zaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Sina Kiani Afzali

Position

Specialized Surgical Assistant

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

University Campus of Medical Sciences.,Doctor Hesabi Square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5570

Email

dr.sina.kiani@zaums.ac.ir

Web page address

https://zaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Sina Kiani Afzali

Position
Specialized Surgical Assistant

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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Web page address
https://zaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Sina Kiani Afzali

Position
Specialized Surgical Assistant

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Phone
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Email
dr.sina.kiani@zaums.ac.ir

Web page address
https://zaums.ac.ir

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
The final result will be provided in the format of the application form of the Research and Technology Deputy of the university for publication to the Knowledge Translation section of Zahedan University of Medical Sciences.

When the data will become available and for how long
It will be one year after the implementation of the project.

To whom data/document is available
University students and researchers

Under which criteria data/document could be used
not applicable

From where data/document is obtainable
Please refer to Dr. Sina Kiani Afzali at the surgery department of Ali Ibn Abi Talib Hospital in Zahedan.

What processes are involved for a request to access data/document
Please refer to Dr. Saman Kiani Afzali at the surgery department of Ali Ibn Abi Talib Hospital in Zahedan.

Comments