

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of open drainage, closed drainage and absence of drainage on abdominal collection in cholecystectomy patients

Protocol summary

Study aim

The aim of the study will be to compare open drainage, closed drainage and absence of drainage on abdominal collection post-cholecystectomy

Design

Randomized clinical trial with control group, with a parallel group design of 150 patients, phase 3. The randomization function of Excel software will be used for randomization.

Settings and conduct

This study will be conducted as a randomized clinical trial with a control group and without blinding in Besat Hospital in Hamdan, on patients undergoing cholecystectomy. In this study, after cholecystectomy, in order to discharge the blood and secretions from the surgical site, one group will have an open drainage, the second group will have a closed drainage, and the third group will have no drainage at the surgical site. One week after the surgery, the abdominal area will be checked for collection by ultrasound.

Participants/Inclusion and exclusion criteria

The participants will be patients candidates for cholecystectomy. The age of 18 to 80 years is the conditions for entering the study and having a history of abdominal surgery, heart disease, heart transplant and taking immunosuppressive drugs are the conditions of not entering the study.

Intervention groups

Three parallel intervention groups, the first and second group after surgery, will be repaired at the cholecystectomy site with a drainage. Open drain will be used in the first group and closed drain will be used in the second group. In the third group, the operation was done in a standard method and the operation site will be repaired without inserting a drainage

Main outcome variables

Post cholecystectomy abdominal collection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N30**

Registration date: **2023-05-15, 1402/02/25**

Registration timing: **prospective**

Last update: **2023-05-15, 1402/02/25**

Update count: **0**

Registration date

2023-05-15, 1402/02/25

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of open drainage, closed drainage and absence of drainage on abdominal collection in cholecystectomy patients

Public title

Effect of drainage on the intra-abdominal of cholecystectomy collection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate for cholecystectomy

Exclusion criteria:

History of abdominal surgery Patients with congenital and acquired immune deficiency

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

We made 150 cards and write letters OD on 50 cards for Open Drainage, CD on 50 cards for closed Drainage and on the other 50 letters ND for No Drainage group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and open it, based on selected letter patients will be assigned to open drainage, closed drainage or no drainage groups.

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 Hamadan University of Medical Science

Street address

Shahid Fahmideh Ave

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6517838697

Approval date

2023-05-06, 1402/02/16

Ethics committee reference number

IR.UMSHA.REC.1402.105

Health conditions studied

1

Description of health condition studied

Acute cholecystitis

ICD-10 code

K80.0

ICD-10 code description

Calculus of gallbladder with acute cholecystitis

Primary outcomes

1

Description

Abdominal collection

Timepoint

One week post-surgery

Method of measurement

Abdominal ultrasound

Secondary outcomes

1

Description

Pain Severity

Timepoint

24 hours post-surgery

Method of measurement

With Visual Analogue Scale

Intervention groups

1

Description

Intervention group: This group will be operated under open drain. For this purpose, after the surgery , a tube, which is closed on both sides, is placed on one side of the surgical site, and the other side of the tube is outside to discharge the blood and secretions from the surgical site to the outside of the body.

Category

Treatment - Devices

2

Description

Intervention group: The second group will be under a closed drain. A tube that is open on one side and is

placed in the surgical site. The other side of the tube has a bag to collect blood and secretions from the surgical site.

Category

Treatment - Devices

3**Description**

Control group: In this group, the surgical site will be sutured without inserting a drain .

Category

Treatment - Other

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

Besat Hospital

Full name of responsible person

Dr Roholla Hosseini

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Reza Shokohi

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

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

MSc in epidemiology/ Community Medicine MS

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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