

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of drain following an uncomplicated laparoscopic cholecystectomy

Protocol summary

Summary

Objectives: Determine the effect of drainage on postoperative complications of laparoscopic cholecystectomy. Design: Randomized, single-blind, single-center, phase II trial. Setting and conduct: For group A, drain is placed within substrate of liver at the end of the location of surgery and for group B, drain is not placed. Postoperative pain, hospital stay and infection drains and needed a second surgery is measured in two groups. Inclusion criteria include patients undergoing drains for laparoscopic cholecystectomy; exclusion criteria include conversion of laparoscopic surgery to open surgery. Intervention: drain is placed for intervention group and drain is not placed for control group. Main outcome measures variable: Pain after placement of drain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016013126281N1**

Registration date: **2016-03-03, 1394/12/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-03, 1394/12/13

Registrant information

Name

Mahmoud Heydari

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3821 1291

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of drain following an uncomplicated laparoscopic cholecystectomy

Public title

Efficacy of drain on uncomplicated of cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients undergoing drains for laparoscopic cholecystectomy. Exclusion criteria: Conversion of laparoscopic surgery to open surgery.

Age

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

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of
Medical Sciences

Street address

Building No 1, Kermanshah University of Medical
Sciences, Shahid Beheshti Blvd.

City

Kermanshah

Postal code

Approval date

2015-02-17, 1393/11/28

Ethics committee reference number

53288

Health conditions studied

1

Description of health condition studied

Biliary colic

ICD-10 code

K80.5

ICD-10 code description

Calculus of bile duct without cholangitis or cholecystitis

Primary outcomes

1

Description

Pain

Timepoint

12 h and 24 h after drain placement

Method of measurement

According to the VAS scale

2

Description

Nausea and vomiting

Timepoint

12 h and 24 h after drain placement

Method of measurement

According to the visual scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Placement of drain in substrate of
liver at the end of operation

Category

Treatment - Surgery

2

Description

Control group: Non-placement of drain in substrate of
liver at the end of operation

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mahmoud Heydari

Street address

Surgery Department, Imam Reza Hospital,
Sorkhalizheh.

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University
of Medical Sciences

Full name of responsible person

Behrozeh Hamzeh

Street address

Building No 2, Kermanshah University of Medical
Sciences, Shahid Beheshti Blvd. Kermanshah

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical sciences

Full name of responsible person

Behnam Reza Makhsoosi

Position

Specialist in General Surgery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty