Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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mheydari@kums.ac.ir

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

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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 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