Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of drainage on post operation complications in uncomplicated laparoscopic cholecystectomy

Protocol summary

Summary

The aim of this study is to investigate the effect of drainage on post operation complications in uncomplicated laparoscopic cholecystectomy. In this non-randomized clinical trial, 86 patients with biliary colic undergoing Laparoscopic cholecystectomy and meet the inclusion and exclusion criteria, are randomly assigned in the intervention or control groups. In the intervention group the drain is placed in the bed of the liver at the end of operation but will not be embedded in the control group. Collection, postoperative pain, hospital stay, drain site infection and needed back surgery were measured and compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109147542N1**
Registration date: **2011-10-01, 1390/07/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-10-01, 1390/07/09

Registrant information

Name

Hassan Talebzadeh Farooji

Name of organization / entity

Kashan University of Medical Sciences

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Phone

+98 36 1562 0320

Email address

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of drainage on post operation complications in uncomplicated laparoscopic cholecystectomy

Public title

The effect of drainage on post operation complications in uncomplicated laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 18 to 80 years old with biliary colic undergoing laparoscopic cholecystectomy with no complications during the procedure (damage to internal viscera), not experience Exclusion criteria: any complications in laparoscopic cholecystectomy during laparoscopic surgery, which it sees, a history of abdominal surgery, Laparoscopic surgery for more than one hour

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Kashan University of Medical Sciences

Street address

5th km of Ravandi ghotb Blv

City

Kashan

Postal code

8713781147

Approval date

2011-08-09, 1390/05/18

Ethics committee reference number

1383/1/5/29/پ

Health conditions studied

1

Description of health condition studied

biliary colic

ICD-10 code

K81.1

ICD-10 code description

Chronic cholecystitis

Primary outcomes

1

Description

postoperative pain

Timepoint

24 hour after surgery

Method of measurement

visual analog scale

2

Description

Fluid accumulation in the liver bed

Timepoint

Seven days after surgery

Method of measurement

The ultrasound

3

Description

Hospital stay

Timepoint

Discharge

Method of measurement

day

4

Description

The recovery rate

Timepoint

Seven days after surgery

Method of measurement

No need for surgical intervention during the first seven days after surgery

Secondary outcomes

1

Description

Back Surgery

Timepoint

During the first seven days after surgery

Method of measurement

Complications requiring reoperation

2

Description

Drain site infection

Timepoint

When you pull the drain on the second day

Method of measurement

The View

Intervention groups

1

Description

Intervention group: placement of drains in the liver bed after laparoscopic cholecystectomy

Category

Treatment - Surgery

2

Description

Control group: drain won’t be inserted into the liver bed after laparoscopic cholecystectomy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital, Kashan
Full name of responsible person
Mohammad Eidi
Street address
Beheshti Hospital, 5th km of ghotb ravandi Blvd, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences research
Full name of responsible person
Gholamali Hamidi
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Kashan University of Medical Sciences research, 5th km ravandi ghotb Blvd, Kashan
City
Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences research
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

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Name of organization / entity
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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