

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 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

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**

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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+98 83 3721 2766

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Drmakhsosy@yahoo.com

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

Mahmoud Heydari

**Position**

Resident of General Surgery

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

Mahmoud Heydari

**Position**

Resident of General Surgery

**Other areas of specialty/work**

**Street address**

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**Email**

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**Web page address**

## 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*