

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Assessing effect of endo-bag on the complications of cholecystectomy laparoscopic surgery

#### Protocol summary

##### Study aim

Determination effect of endo-bag on the complications of cholecystectomy laparoscopic surgery

##### Design

This study will be conducted as a randomized, double-blind clinical trial

##### Settings and conduct

Patients who are eligible for inclusion in the study are included in the study and without knowing it whether the surgery has an endo-bag or not, surgery happens to them. Only surgeon and person who enters the patient into the operating room knows endo-bag or not. Patients are operated in the operating room of Imam Khomeini Hospital in Kermanshah.

##### Participants/Inclusion and exclusion criteria

Having an acute gall bladder infection problem and ages between 18 and 65 years old; History of cystectomy surgery and having liver cirrhosis

##### Intervention groups

The intervention in this study is applying the endo-bag. Surgeon putting the endo-bag (when is closed) into the patient's abdomen and opens it at the surgical site with special lever. Then the contents of the surgery, which is high volume and can not be removed from Laparoscopic small incision it is placed in the endo-bag and is brought to a nearby surgical site and fragmentary going out. Intervention group are patients who eligible for inclusion in the study and without knowing about their surgery have with endo-bag or without endo-bag. Then surgery with endo-bag applied to them. Control group are patients who eligible for inclusion in the study and without knowing about their surgery have with endo-bag or without endo-bag. Then surgery without endo-bag applied to them.

##### Main outcome variables

1- Pain due to laparoscopic cholecystectomy 2- Duration of surgery for laparoscopic cholecystectomy 3- Collection of Morrison area in laparoscopic cholecystectomy 4- Wound infection after laparoscopic cholecystectomy 5-

Ileus after laparoscopic cholecystectomy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100609004141N2**

Registration date: **2018-12-14, 1397/09/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-14, 1397/09/23**

Update count: **0**

##### Registration date

2018-12-14, 1397/09/23

##### Registrant information

##### Name

ezatollah sadeghi

##### Name of organization / entity

kermanshah university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1427 6325

##### Email address

dr.makhsosy@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-01, 1397/05/10

##### Expected recruitment end date

2018-12-21, 1397/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Assessing effect of endo-bag on the complications of cholecystectomy laparoscopic surgery

**Public title**

Assessing effect of endo-bag on the complications of cholecystectomy laparoscopic surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having an acute gall bladder infection problem Ages between 18 and 65 years old

**Exclusion criteria:**

History of cystectomy surgery Having liver cirrhosis

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The assignment of patients to each group will be applied based on randomization block to control the effect of age and sex. And so on the proportion of sex (women and men) and age (under 40, 40 years old and more) will be approximately the same in the two groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the patients and the peoples how measuring the variables would be unaware of the presence of patients in the endo-bag or non endo-bag groups. Only the surgeon aware about grouping, after of ending the evolution of necessary variables, groups of each person will be spesified in cheklist, based on coding system.

**Placebo**

Not 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**

Deputy of Research and Technology , Shahid Beheshti Blvd, Building No. 2 , Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2018-07-24, 1397/05/02

**Ethics committee reference number**

IR.KUMS.REC.1397.365

**Health conditions studied****1****Description of health condition studied**

Effect of endo-bag on the complications of cholecystectomy laparoscopic surgery

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

1- Pain due to laparoscopic cholecystectomy2- Duration of surgery for laparoscopic cholecystectomy3- Collection of Morrison area in laparoscopic cholecystectomy4- Wound infection after laparoscopic cholecystectomy5- Ileus after laparoscopic cholecystectomy

**Timepoint**

Immediately after surgery and up to 3 months after surgery

**Method of measurement**

Visual Assessment Scale of Pain 0-10

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention: The intervention in this study is applying the endo-bag. Endo-bag is a gadget, like a bag that can be inserted into the surgical wound and it can be opened and closed with control from the outside of the abdomen. Surgeon putting the endo-bag (when is closed) into the patient's abdomen and opens it at the surgical site with special lever. Then the contents of the surgery, which is

high volume and can not be removed from Laparoscopic small incision it is placed in the endo-bag and is brought to a nearby surgical site and fragmentary going out. Intervention group are patients who eligible for inclusion in the study and without knowing about their surgery have with endo-bag or without endo-bag. Then surgery with endo-bag applied to them

**Category**

Treatment - Surgery

**2****Description**

Control group are patients who eligible for inclusion in the study and without knowing about their surgery have with endo-bag or without endo-bag. Then surgery without endo-bag applied to them.

**Category**

Treatment - Surgery

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

Imam Khomeini hospital in Kermanshah

**Full name of responsible person**

Dr Behnam Reza Makhsosy

**Street address**

Imam Khomeini hospital in Kermanshah

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6718743161

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**Email**

ihosp@kums.ac.ir

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

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr Farid Najafi

**Street address**

Deputy of Research and Technology , Shahid Beheshti Blvd, Building No. 2 , Kermanshah

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farid\_n32@yahoo.com

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

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr Behnam reza Makhsosy

**Position**

Managing Director of Imam Khomeini Hospital in Kermanshah

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

**Street address**

Imam Khomeini hospital in Kermanshah, Naghliye avenue , Kermanshah

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr Behnam reza Makhsosy

**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Sharmin rahmani

**Position**

Researcher of research Unit, Imam Khomeini Hospital,  
Kermanshah

**Latest degree**

Master

**Other areas of specialty/work**

Biostatistics

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sh.rahmani90@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

After the samples being unidentifiable, data is  
publishable .

**When the data will become available and for how long**

The access period; Starts 6 months after publishing the  
results

**To whom data/document is available**

Researchers working in academic and scientific  
institutions

**Under which criteria data/document could be used**

People who try to help science can use data.

**From where data/document is obtainable**

Expert of Research Unit of Imam Khomeini Hospital in  
Kermanshah , Sharman Rahmani ,  
sh.rahmani90@yahoo.com

**What processes are involved for a request to access data/document**

1- Send a request to sh.rahmani90@yahoo.com 2. The  
purpose of the data request, stated clearly. 3- If  
confirmed by the main executor, immediately proceed.

**Comments**