Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 evoluation 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

City

Kermanshah

Province

Kermanshah

Postal code

6718743161

Phone

+98 83 3728 5054

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

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3838 4185

Email

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

City

Kermanshah

Province

Kermanshah

Postal code

6718743161

Phone

+98 83 3728 5054

Email

dr.makhsosy@kums.ac.ir

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

Managing Director of Imam Khomeini Hospital in Kermanshah

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Province
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Postal code
6718743161
Phone
+98 83 3728 5054
Email
dr.makhsosy@kums.ac.ir

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
Street address
Imam Khomeini hospital in Kermanshah, Naghliye avenue , Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
6718743161
Phone
+98 83 3727 2049
Email
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