Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of Comparative of the consequences of laparoscopic cholecystectomy with two surgical methods of right and left abdominal port

Protocol summary

Study aim
Assessment of Comparative of the consequences of laparoscopic cholecystectomy with two surgical methods of right and left abdominal port

Design
A clinical trial with a control group and a parallel group was randomized. Phase 2-3, on 80 patients who were candidates for cholecystectomy with single blinded, was used to randomize the randomized block method.

Settings and conduct
This clinical trial study is performed in Imam Hossein Hospital in Tehran. Patients divide two forty groups of right and left abdominal port.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with symptomatic cholelithiasis and acute and chronic cholecystitis.
Exclusions criteria: pregnancy, morbid obesity, common bile duct stones, Obstructive jaundice, cirrhosis, uncorrectable coagulopathy, previous surgery in the upper abdomen

Intervention groups
laparoscopic cholecystectomy with two surgical methods of right and left abdominal ports

Main outcome variables
Duration of surgery, duration of hospitalization, postoperative pain, change of method to open surgery and complications of postoperative surgery will be evaluated between the two groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160523028008N20**
Registration date: **2022-01-25, 1400/11/05**
Registration timing: **prospective**
Last update: **2022-01-25, 1400/11/05**
Update count: **0**

Registration date
2022-01-25, 1400/11/05

Registrant information

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Name of organization / entity
Hamadan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-14, 1400/11/25

Expected recruitment end date
2022-04-14, 1401/01/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of Comparative of the consequences of laparoscopic cholecystectomy with two surgical methods of right and left abdominal port

Public title
laparoscopic cholecystectomy with two surgical methods of right and left abdominal port

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with symptomatic cholelithiasis and acute and chronic cholesistitis.
Exclusion criteria:
pregnancy morbid obesity common bile duct stones Obstructive jaundices cirrhosis uncorrectable coagulopathy previous surgery in the upper abdomen
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action is repeated until the sample size is reached.
Blinding (investigator's opinion)
Single blinded
Blinding description
The patient will be unaware of the type of intervention performed, so the study is performed as single-blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of School of Medicine - Shahid Beheshti University of Medical Sciences
Street address
Faculty of Medicine, Shahid Beheshti University of Medical Sciences, Arabi St., Yaman St., Chamran Highwa
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2021-09-21, 1400/06/30
Ethics committee reference number
IR.SBMU.MSP.REC.1400.434

Health conditions studied

1

Description of health condition studied
Calculus of gallbladder with acute cholecystitis
ICD-10 code
k80.0, K8
ICD-10 code description
Calculus of gallbladder with acute cholecystitis

Primary outcomes

1

Description
Duration of surgery
Timepoint
from the time the skin was cut until the time it was closed
Method of measurement
recorded by surgeon

2

Description
Hospitalization time
Timepoint
from entrance unit until discharge
Method of measurement
numeration of hospitalization days

3

Description
pain after surgery
Timepoint
48 hours after surgery
Method of measurement
measuring levels of pain using visual analog scale(VAS)

4

Description
postoperative narcotic usage
Timepoint
Continuously recorded and measured at the time of discharge
Method of measurement
Patient record

5

Description
Change method to open surgery
Timepoint
Time of surgery
Method of measurement
recorded by surgeon

Secondary outcomes

1

Description
Nausea and vomiting after surgery
Timepoint
in the first 48 hours after surgery
Method of measurement
subjective, recorded by observer from the questionnaire

2

Description
Medical complications after surgery (bedding, damage of bile ducts,
Timepoint
After surgery
Method of measurement
based on medical chart

Intervention groups

1

Description
Intervention group: 3 ports laparoscopic in patient with gallstone and colisistit right abdominal.
Category
Treatment - Devices

2

Description
Intervention group: 3 ports laparoscopic in patient with gallstone and colisistit left abdominal.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hussein Hospital
Full name of responsible person
Majid Samsami
Street address
Imam Hussein Hospital, Madani St, Nezam-Abad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, Arabi St., Yaman St., Chamran Highway
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Majid Samsami
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No - There is not a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available