

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Mohammad Faryadras

Name of organization / entity

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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 cholecystitis.

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 colicistit right abdominal.

Category

Treatment - Devices

2

Description

Intervention group: 3 ports laparoscopic in patient with gallstone and colicistit 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

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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 scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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

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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