Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the outcomes of early cholecystectomy compared to delayed cholecystectomy after ERCP

Protocol summary

Study aim

1- Determining and comparing the frequency distribution of laparoscopic surgery to open surgery 2- Determining and comparing the average amount of intraoperative bleeding 3- Determining and comparing the frequency distribution of bile leak from the drain after surgery 4- Determining and comparing the average duration of surgery 5- Determining and comparing the frequency distribution of visceral and bile duct damage during and after surgery 6- Determining and comparing the frequency distribution of the need for ERCP reoperation after surgery 7- Determining and comparing the frequency distribution of infection at the site of postoperative surgery 8- Determining and comparing the average duration of postoperative hospitalization

Design

A randomized, single blind, randomized, clinical trial on 188 patients. For randomization, the method of 2 random blocks is used.

Settings and conduct

Interventional study, randomized clinical trial and single blind,Applied approach in Isfahan medicinal teaching hospitals

Participants/Inclusion and exclusion criteria

Entry requirement: Patients over 18 years old with cholecholithiasis who are candidates for ERCP and then cholecystectomy No entry conditions: 1. Intolerance to general anesthesia 2. Severe liver and kidney dysfunction 3. Patients who refuse surgery 4. Occurrence of pancreatitis after performing ERCP

Intervention groups

Patients are divided into two groups after ERCP and in one group early cholecystectomy is performed and in the other group delayed cholecystectomy is performed

Main outcome variables

Local infection; duration of surgery; bleeding during surgery; conversion to open surgery; bile leakage from drain after surgery; damage to viscera and bile ducts during surgery; need for ERCP again after surgery; duration Hospitalization after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201013049017N3**
Registration date: **2022-10-12, 1401/07/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-12, 1401/07/20**
Update count: **0**

Registration date

2022-10-12, 1401/07/20

Registrant information

Name
Hamid Talebzadeh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the outcomes of early cholecystectomy compared to delayed cholecystectomy after ERCP

Public title
Evaluation of the time of cholecystectomy after ERCP
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years old with coledocolitiasis who are candidates for ERCP and then cholecystectomy
Exclusion criteria:
Intolerance to general anesthesia Severe liver and kidney dysfunction Patients who refuse surgery Occurrence of pancreatitis after ERCP
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **188**
Randomization (investigator's opinion)
Randomized
Randomization description
For sampling, the method of double random blocks with SPSS software is used. In this way, two people who come for surgery are considered as one block until the number of blocks reaches 94. Then one person from each block is randomly assigned by the early method and one person by the delayed method.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants are randomly assigned to receive one type of intervention, and only researchers know which participants are in which group, but participants do not know
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Sofeh Blvd,Al-Zahra Hospital
City
Isfahan
Province
Isfehan
Postal code
8174675731
Approval date
2022-03-08, 1400/12/17
Ethics committee reference number
IR.MUI.MED.REC.1400.835

Health conditions studied

1

Description of health condition studied
Cholecystitis,Choldocolithiasis
ICD-10 code
K80.5
ICD-10 code description
Calculus of bile duct without cholangitis or cholecystitis

Primary outcomes

1

Description
Local infection
Timepoint
7 days after surgery
Method of measurement
File Reading and Physical Examination

2

Description
Duration of surgery
Timepoint
During surgery
Method of measurement
File Reading

3

Description
Bleeding during surgery
Timepoint
During surgery
Method of measurement
File Reading

4

Description
Conversion to open surgery
Timepoint
During Surgery
Method of measurement

File reading

5

Description
Bile leakage from the drain
Timepoint
one day after the surgery
Method of measurement
File Reading

6

Description
Damage to internal organs and bile ducts
Timepoint
During surgery
Method of measurement
File reading

7

Description
Need for repeat ERCP
Timepoint
7 days after surgery
Method of measurement
File Reading and Physical Examination

8

Description
Duration of hospitalization
Timepoint
7 days after surgery
Method of measurement
File reading

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: early cholecystectomy - in this group, the time interval between ERCP and cholecystectomy is less than 6 days. All patients are NPO 6 hours before the operation. Vital signs, heart monitoring and routine tests will be done for all patients.Laparoscopic cholecystectomy operation will be performed as 4 ports (subxiphoid, preumbilical ports with 10 mm incisions, midclavicular and anterior axillary ports with 5 mm incisions). The rate of conversion of laparoscopic surgery to open surgery, the amount of bleeding, the average duration of surgery, the amount of damage to viscera and bile ducts during the operation will be recorded. The average duration of hospitalization and the amount of bile leakage from the drain after surgery will be extracted from his file and recorded. The rate of need for repeat ERCP and the rate of infection at the surgical site after the operation will also be recorded through the follow-up of the patient's condition. After recording the extracted data and statistical analysis, the obtained results will be analyzed and written.
Category
Treatment - Surgery

2

Description
The second intervention group: late cholecystectomy - in this group, the time interval between ERCP and cholecystectomy is more than 6 days. All patients are NPO 6 hours before the operation. Vital signs, heart monitoring and routine tests will be done for all patients.Laparoscopic cholecystectomy operation will be performed as 4 ports (subxiphoid, preumbilical ports with 10 mm incisions, midclavicular and anterior axillary ports with 5 mm incisions). The rate of conversion of laparoscopic surgery to open surgery, the amount of bleeding, the average duration of surgery, the amount of damage to viscera and bile ducts during the operation will be recorded. The average duration of hospitalization and the amount of bile leakage from the drain after surgery will be extracted from his file and recorded. The rate of need for repeat ERCP and the rate of infection at the surgical site after the operation will also be recorded through the follow-up of the patient's condition. After recording the extracted data and statistical analysis, the obtained results will be analyzed and written.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin Hospital
Full name of responsible person
Hamid Talebzadeh
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
Hamid Talebzadeh

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash Dastjerdi
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research@mui.ac.ir
Web page address
https://mui.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Hamid Talebzadeh
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Subspecialist
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Person responsible for updating data

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after deidentifying individuals

When the data will become available and for how long

The access period starts after the results are printed

To whom data/document is available

People who are engaged in the industry can apply for them.

Under which criteria data/document could be used

In all circumstances

From where data/document is obtainable

Internet networks

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

By search

Comments