Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the outcome of bile leakage in the use of one hemolock clip to close the cystic duct in laparoscopic cholecystectomy

Protocol summary

Study aim
Determining bile leak after closing the cystic duct with a hemolock clip in cholecystectomy Laparoscopic

Design
This study will be a clinical trial, case series. 40 cases of patients who underwent laparoscopic cholecystectomy surgery and a number of hemoloc clips are used to close the cystic duct will be included in the study. Data recorded 24 to 72 hours after cholecystectomy will be evaluated for bile leak and cystic duct patency by MRCP. In addition, during one week after the surgery, the intensity of pain, the possibility of biliary peritonitis up to two weeks after the surgery, and the formation of biloma up to three months after the surgery will be checked.

Settings and conduct
In this study, 40 samples will be selected from among the patients who underwent laparoscopic cholecystectomy surgery in Imam Reza and Imam Khomeini hospitals of Ardabil University of Medical Sciences and a clip was used to close their ducts. Sampling method will be available.

Participants/Inclusion and exclusion criteria
candidate for laparoscopic cholecystectomy Age range from 30 to 60 years operated by a surgeon Willingness to participate in the study

Intervention groups
This study will be a Series Case. 40 cases of patients who underwent laparoscopic cholecystectomy surgery and a number of hemoloc clips are used to close the cystic duct will be included in the study. Data recorded 24 to 72 hours after cholecystectomy will be evaluated for bile leak and cystic duct patency by MRCP. In addition, during one week after the surgery, the intensity of pain, the possibility of biliary peritonitis up to two weeks after the surgery, and the formation of biloma up to three months after the surgery will be checked.

Main outcome variables
Biliary peritonitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100628004256N10**
Registration date: **2023-09-28, 1402/07/06**
Registration timing: **prospective**

Last update: **2023-09-28, 1402/07/06**
Update count: **0**

Registration date
2023-09-28, 1402/07/06

Registrant information

Name
Nasrin Samadi

Name of organization / entity
Ardabil University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 45 1551 3057

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the outcome of bile leakage in the use of one hemolock clip to close the cystic duct in laparoscopic cholecystectomy

Public title
Investigating the outcome of bile leakage in the use of one hemolock clip to close the cystic duct in laparoscopic cholecystectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
candidate for laparoscopic cholecystectomy Age range from 30 to 60 years operated by a surgeon Willingness to participate in the study.
Exclusion criteria:

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic Committees of Ardabil University of Medical Sciences
Street address
Daneshgah st
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۸۹-۸۵۹۹۱

Approval date
2023-08-03, 1402/05/12

Ethics committee reference number
IR.ARUMS.REC.1402.109

Health conditions studied

1

Description of health condition studied
cholecystitis

ICD-10 code
K80-K87, K

ICD-10 code description
Disorders of gallbladder, biliary tract and pancreas, Diseases of peritoneum

Primary outcomes

1

Description
Pain

Timepoint
weeks after cholecystectomy

Method of measurement
Evaluation with a pain virtual scale of 0 to 10

2

Description
Biliary peritonitis

Timepoint
2 weeks after cholecystectomy

Method of measurement
Examination by a surgeon and MRCP

3

Description
Biloma

Timepoint
3 months after cholecystectomy

Method of measurement
Examination by a surgeon and MRCP

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One hemoloc clip will be used to close the cystic duct. 24 to 72 hours after cholecystectomy, bile leak and openness of the cystic duct will be checked by MRCP. In addition, during one week after the surgery, the intensity of pain, the possibility of biliary peritonitis up to two weeks after the surgery, and the formation of biloma up to three months after the surgery will be checked.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital of Ardabil
Full name of responsible person
Dr Saeed Shahi
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Daneshgah st
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Dr Saeed Shahi
Position
surgeon
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)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available