

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 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 hemolock 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 hemolock 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)

Phone

+98 45 1551 3057

Email address

na.samadi@arums.ac.ir

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 hemolock 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

Street address

Daneshgah st

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Phone

+98 914 682 9709

Email

na.samadi@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Saeed Shahi

Street address

Daneshgah st

City

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Postal code

۵۶۱۸۹-۸۵۹۹۱

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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

Street address

Daneshgah st

City

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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