

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Outcomes of Early and Delayed laparoscopic Cholecystectomy in Patients with Acute Biliary Pancreatitis.

Protocol summary

Study aim

Determination of the Effect of Early and Delayed Laparoscopic Cholecystectomy in Patients with Mild to moderate Acute Biliary Pancreatitis

Design

208 patients with mild to moderate ABP were prospectively randomized to either an early cholecystectomy group (104 patients) or delayed Cholecystectomy group (104 patients).

Settings and conduct

This is a clinical randomized controlled study including all patients have mild to moderate ABP who met the inclusion criteria. The study was performed at kashan shahid beheshti general Hospital, Iran. A total of 208 patients were enrolled. Of them, 104 were randomized to the early group and 104 patients to the delayed group. To demonstrate a reduction of recurrent biliary events with power of 9% and two sided test of 5%, 104 patients will have to be included in each group. Clinical signs of pancreatitis, e.g., upper abdominal pain, nausea, vomiting, and epigastric tenderness; (2) an elevated serum amylase level of at least thrice the upper limit of normal; and presence of stones in the gallbladder or biliary ducts. On ultra-solography, computed tomography (CT) or magnetic resonance imaging (MRI).

Participants/Inclusion and exclusion criteria

Inclusion Criteria: All patients aged 18 to 81 years with clinical diagnosis of acute mild to Moderate biliary pancreatitis. Exclusion Criteria: Pregnancy, Pancreatitis due to alcohol abuse, Cholecystitis necrotizing pancreatitis, cholecystitis Cholangitis.

Intervention groups

Early cholecystectomy: Laparoscopic cholecystectomy was done during the first 48 hours of admission in patients with biliary pancreatitis. Delay cholecystectomy: Laparoscopic cholecystectomy was done after 7 days.

Main outcome variables

Difficulty of cholecystectomy, Operative time, Cholecystectomy related complications, Hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038627N2**

Registration date: **2019-05-21, 1398/02/31**

Registration timing: **retrospective**

Last update: **2019-05-21, 1398/02/31**

Update count: **0**

Registration date

2019-05-21, 1398/02/31

Registrant information

Name

Abdoulhossein Davoodabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5554 3154

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davoodabadi_ab@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-18, 1397/02/28

Expected recruitment end date

2019-04-09, 1398/01/20

Actual recruitment start date

2018-05-18, 1397/02/28

Actual recruitment end date

2019-03-21, 1398/01/01

Trial completion date

2019-04-17, 1398/01/28

Scientific title

Comparison of Outcomes of Early and Delayed laparoscopic Cholecystectomy in Patients with Acute Biliary Pancreatitis.

Public title

Assessment of Early Cholecystectomy in mild to moderate Acute Biliary Pancreatitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients aged 18 to 81 years with acute mild to Moderate biliary pancreatitis

Exclusion criteria:

pancreatitis due to alcohol abuse and cholecystitis
necrotizing pancreatitis pregnancy cholecystitis
Cholangitis

Age

From **18 years** old to **81 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **208**

Actual sample size reached: **208**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random numbers

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd.

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2018-05-03, 1397/02/13

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.006

Health conditions studied

1

Description of health condition studied

cholecystectomy

ICD-10 code

Z90.4

ICD-10 code description

Acquired absence of other parts of digestive tract

Primary outcomes

1

Description

Operative time

Timepoint

At the end of surgery

Method of measurement

Clock

2

Description

Difficulty of cholecystectomy

Timepoint

At the end of surgery

Method of measurement

Ask the surgeon with likert scale

3

Description

Hospital stay after surgery

Timepoint

At the time of discharge

Method of measurement

Based on medical records

4

Description

Cholecystectomy related complications

Timepoint

At the time of discharge and 30 days later

Method of measurement

Descriptive history and clinical records

Secondary outcomes

empty

Intervention groups

1

Description

Group I: Comprised of 104 patients with acute mild to Moderate biliary pancreatitis were operated during the 48 hours. laparoscopic Cholecystectomies were done by expert surgeon. LC was carried out with three ports technique . An additional fourth port was used when required. All dissections were performed with the harmonic scalpel.C-reactive protein (CRP) level was used to monitor patient progress.

Category

Treatment - Surgery

2

Description

Group 2: Comprised of 104 patients with acute mild to Moderate Biliary Pancreatitis were operated. after 7 days. laparoscopic Cholecystectomies were done by expert surgeon. LC was carried out with three ports technique . An additional fourth port was used when required. All dissections were performed with the harmonic scalpel.C-reactive protein (CRP) level was used to monitor patient progress.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Beheshti Hospital

Full name of responsible person

Mohammad Reza Fazel

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

عبدالحسين داودآبادی

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Thoracic surgery

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Person responsible for scientific inquiries

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All of collected primary outcome and data measure after intervention will be shared .

When the data will become available and for how long

20 years after publication

To whom data/document is available

general population

Under which criteria data/document could be used

no any require criteria

From where data/document is obtainable

email addresses

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

no any specific processes require

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

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