

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison the therapeutical outcomes between common bile duct (CBD) stenting and standard endoscopic treatment in patient with CBD stones and multiple gallbladder stones

Protocol summary

Study aim

Comparison the therapeutical outcomes between common bile duct (CBD) stenting and standard endoscopic treatment in patient with CBD stones and multiple gallbladder stones

Design

Randomized controlled trial, with two arm parallel group of 40 patients, will be enrolled between September 2018 and March 2019, and will follow for 1 month

Settings and conduct

In this research, 40 eligible patients needed endoscopic retrograde cholangiopancreatography referring to Qom gastroenterology clinic were chosen. Then, patients by block randomization were randomly divided into two control and intervention groups. The intervention group will receive common bile duct stenting and control group will receive standard endoscopic retrograde cholangiopancreatography. Participants does not know the intervention type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with CBD stones and multiple gallbladder stones. Exclusion criteria: history of bile duct surgery; history of stomach and duodenal surgery; history of cholecystectomy

Intervention groups

Intervention group: common bile duct stenting. Control group: standard endoscopic retrograde cholangiopancreatography

Main outcome variables

Stone migration from gallbladder to common bile duct

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161205031252N9**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **prospective**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Ahmad Hormati

Name of organization / entity

Qom university of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the therapeutical outcomes between common bile duct (CBD) stenting and standard endoscopic treatment in patient with CBD stones and

multiple gallbladder stones

Public title

Common bile duct stenting treatment in patient with CBD stones and multiple gallbladder stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with CBD stones and multiple gallbladder stones

Exclusion criteria:

History of bile duct surgery
History of stomach and duodenal surgery
History of cholecystectomy
High risk for cardiovascular and respiratory events
Bleeding disorders
Radiotherapy history

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be assigned to two groups of intervention and control by block randomization. For this purpose blocks of size 4 will be used. Six blocks will include BAAB, ABBA, BABA, BBAA, ABAB, AABB. To hide the random allocation, the numbered dark envelopes will be used, in which the group name is specified in the random sequence generated. Then, according to the order of entering samples, for the first patient the envelope number one is opened and the group will be identified until the end.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants does not know the allocation

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qom University of Medical Sciences

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Qom University of Medical Sciences, Saheli street,

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3713649373

Approval date

2018-09-11, 1397/06/20

Ethics committee reference number

IR.MUQ.REC.1397.085

Health conditions studied

1

Description of health condition studied

Common bile duct stones

ICD-10 code

K80

ICD-10 code description

Cholelithiasis

Primary outcomes

1

Description

Stone migration from gallbladder to common bile duct

Timepoint

1 month after treatment

Method of measurement

Endoscopic retrograde cholangiopancreatography

Secondary outcomes

1

Description

Cholangitis

Timepoint

After endoscopic retrograde cholangiopancreatography

Method of measurement

According to Charcot's triad including abdominal pain, serum bilirubin measurement and core body temperature measurement

2

Description

Pancreatitis

Timepoint

After endoscopic retrograde cholangiopancreatography

Method of measurement

Serum Amylase level measurement

Intervention groups

1

Description

Intervention group: Common bile duct stenting

Category

Treatment - Devices

2

Description

Control group: Standard Endoscopic retrograde cholangiopancreatography

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hosbital

Full name of responsible person

Ahmad Hormati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous 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

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Ahmad Hormati

Position

Assistant Professor of Gastroenterology

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Latest degree

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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

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