Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Ahmad Hormati

Name of organization / entity
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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
Street address
Qom University of Medical Sciences, Saheli street, Qom
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Qom
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Ghoum
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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
Chollangitis
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
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Sponsors / Funding sources

1

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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
Ghoum 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
Ghoum University of Medical Sciences
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Position
Assistant Professor of Gastroenterology
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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