

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of adding ursodeoxycholic acid to common bile duct (CBD) stenting for treatment of large and multiple CBD stones

Protocol summary

Study aim

The effect of adding ursodeoxycholic acid to common bile duct (CBD) stenting for treatment of large and multiple CBD stones

Design

Randomized controlled trial, with two arm parallel group of 64 patients, will be enrolled between September 2018 and March 2019, and will follow for 2 months.

Settings and conduct

In this research, 64 eligible patients needed common bile duct stenting 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 with ursodeoxycholic acid capsule and control group will receive only common bile duct stenting. The study will be done without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: common bile duct stone with a diameter greater than 15mm; More than 3 stones in common bile duct. Exclusion criteria: History of recent surgery on bile ducts; History of gastrectomy; History of duodenal stricture

Intervention groups

Control group: Common bile duct stenting. Intervention group: Common bile duct stenting with Ursodeoxycholic Acid capsule, 300 mg, oral, once daily, for two months

Main outcome variables

Common bile duct clearing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161205031252N8**

Registration date: **2018-08-29, 1397/06/07**

Registration timing: **prospective**

Last update: **2018-08-29, 1397/06/07**

Update count: **0**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Ahmad Hormati

Name of organization / entity

Qom university of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding ursodeoxycholic acid to common bile duct (CBD) stenting for treatment of large and multiple CBD stones

Public title

The effect of ursodeoxycholic acid for treatment of large and multiple common bile duct stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Common bile duct stone with a diameter greater than 15 mm More than 3 stones in common bile duct

Exclusion criteria:

History of recent surgery on bile ducts History of gastrectomy History of duodenal stricture Patients who do not fill the informed concept form

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 64

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)

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 Qom University of Medical Sciences

Street address

No. 83, 4th alley, 1.1 alley, Safashahr Blvd

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Province

Ghoum

Postal code

3716987366

Approval date

2018-07-31, 1397/05/09

Ethics committee reference number

IR.MUQ.REC.1397.075

Health conditions studied

1

Description of health condition studied

CBD stones

ICD-10 code

K80.0

ICD-10 code description

Calculus of gallbladder with acute cholecystitis

Primary outcomes

1

Description

Common bile duct clearing

Timepoint

2 months after CBD stenting

Method of measurement

By 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

3

Description

Reduction in stones size

Timepoint

Two months after common bile duct stenting

Method of measurement

By fluoroscopy during endoscopic retrograde cholangiopancreatography

4

Description

Reduction in common bile duct (CBD) stone number

Timepoint

Two months after CBD stenting
Method of measurement
By endoscopic retrograde cholangiopancreatography

Intervention groups

1

Description
Intervention group: Common bile duct stenting with Ursodeoxycholic Acid capsule, KoushanPharmed company, 300 mg, oral, once daily, for two months
Category
Treatment - Drugs

2

Description
Control group: Common bile duct stenting
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
Ghoum 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
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
Full name of responsible person
Ahmad Hormati
Position
Assistant Professor of adults Gastroenterology and hepatology
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Position

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Latest degree

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Other areas of specialty/work

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Web page address

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

The data are specific to this study

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