

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the therapeutical outcomes between CBD stenting and standard endoscopic treatment in large (grater than 15mm in diameter) and multiple (more than 3) CBD stones

Protocol summary

Summary

The aim of the study is to compare clinical outcome of CBD stenting and standard endoscopic treatment in large(more than 15mm in diameter) or multiple CBD stones.This is a mono centric doble blinded randomized clinical trial. Patients with large or multiple CBD stones enroll the study and in case of recent surgery on bile duct, exclude the study.64 patients will divide in 2 groups randomly, one will receive standard endoscopic treatment and the other will undergo CBD stenting. Stents will be removed within 2 months. clinical outcomes including success rate, pancreatitis, cholangitis , reduction in number and size of stones, isolated pain and rupture will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020831252N4**

Registration date: **2017-11-02, 1396/08/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-02, 1396/08/11

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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hormatia@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2017-02-18, 1395/11/30

Expected recruitment end date

2018-03-22, 1397/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the therapeutical outcomes between CBD stenting and standard endoscopic treatment in large (grater than 15mm in diameter) and multiple (more than 3) CBD stones

Public title

Comparison of CBD stenting and standard endoscopic treatment in large and multiple CBD stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: CBD stone with a diameter greater than 15mm; More than 3 stones in CBD Exclusion criteria: History of recent surgery on bile ducts; History of gastrectomy; History of duodenal stricture; Patients who don not fill the informed concept form

Age

From **18 years** old to **80 years** old

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**Blinding (investigator's opinion)**

Single blinded

Blinding description**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

City

Qom

Postal code

3716987366

Approval date

2015-11-11, 1394/08/20

Ethics committee reference number

IR.MUQ.REC.1394.133

Health conditions studied**1****Description of health condition studied**

CBD stones

ICD-10 code

K80.5, K80

ICD-10 code description

Calculus of bile duct without cholangitis or cholecystitis,
Calculus of bile duct with cholecystitis, Calculus of bile
duct with cholangitis

Primary outcomes**1****Description**

Common bile duct clearing

Timepoint

2 months after CBD stenting

Method of measurement

By ERCP

Secondary outcomes**1****Description**

Cholangitis

Timepoint

After ERCP

Method of measurement

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

2**Description**

Pancreatitis

Timepoint

After ERCP

Method of measurement

Serum Amylase level measurement

3**Description**

Bile ducts perforation

Timepoint

During ERCP

Method of measurement

By ERCP

4**Description**

Reduction in stones size

Timepoint

2 months after CBD stenting

Method of measurement

By ERCP

5**Description**

Reduction in stone number

Timepoint

2 months after CBD stenting

Method of measurement

By ERCP

6**Description**

Isolated pain

Timepoint

After ERCP

Method of measurement

Patient's statements

Intervention groups

1

Description

Common bile duct stenting

Category

Treatment - Devices

2

Description

Standard endoscopic treatment by Endoscopic papillary balloon dilatation

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology and Hepatology Disease Research Center, Qom University of Medical Sciences

Full name of responsible person

Dr Ahmad Hormati

Street address

Gastroenterology and Hepatology Disease Research Center Qom University of Medical Science, Shahid Beheshti Hospital, Qom

City

Qom

Sponsors / Funding sources

1

Sponsor

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Qom University of Medical Sciences

Full name of responsible person

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Gastroenterology and Hepatology Disease Research Center Qom University of Medical Science, Shahid Beheshti Hospital

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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

Qom University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Gastroenterology and Hepatology Disease Research Center, Qom University of Medical Sciences

Full name of responsible person

Dr Ahmad Hormati

Position

Assistant Professor of Gastroenterology

Other areas of specialty/work

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Assistant Professor of Gastroenterology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty