

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jul 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3612 2053

##### Email address

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

#### Name of organization / entity

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

#### City

Qom

### 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

#### Street address

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#### Email

hormatia@yahoo.com

#### Web page address

<http://qddrc.muq.ac.ir/index.aspx>

## Person responsible for scientific 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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## Person responsible for updating data

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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*