

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

A comparative study of one minute versus five seconds endoscopic biliary balloon dilation after small sphincterotomy in choledocolithiasis

Protocol summary

Summary

Limited sphincterotomy and endoscopic papillary balloon dilation (EPBD) is a low risk method in treatment of choledocolithiasis. But effective ballooning time is not clear. In this study, we compare five seconds and one minute ballooning time. This study is a unicentric, single blind, randomized clinical trial. This study is single-blind because participants will be deliberately kept ignorant of either the group to which they will be assigned, but the experimenter will be in possession of the ballooning time in each one. Sixteen to ninety years old patients eligible for treatment of choledocolithiasis, with no severe hepatic, biliary or systemic disease enroll in the study. Lack of consent to cooperate in trial, precut sphincterotomy or failure of cannulation of common hepatic duct will exclude the patient. After initial laboratory examinations, sixty patients randomly will be assigned to receive EPBD with either 5 seconds or one minute ballooning time after endoscopic retrograde cholangiopancreatography and small sphincterotomy. Maximum choledochal diameter, stone or stones count and largest stone diameter will be measured. Then stone or stones will be retrieved with balloon extractor. If stone or stones removed, the procedure is successful. Otherwise, it is unsuccessful. Serum amylase will be checked 2 hours after procedure. Patients will be followed 48 hours for abdominal pain, pancreatitis, perforation, hemorrhage and fever.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013033112877N1**

Registration date: **2013-05-04, 1392/02/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-04, 1392/02/14

Registrant information

Name

Mohammad Hadi Shafigh Ardestani

Name of organization / entity

Isfahan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 31 1668 5555

Email address

mhshafigh@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences and Health Services

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of one minute versus five seconds endoscopic biliary balloon dilation after small sphincterotomy in choledocolithiasis

Public title

Ballooning time after small sphincterotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 16 to 90 years old patients eligible for treatment of choleducolithiasis documented with ultrasonography or magnetic resonance cholangiopancreatography, no severe hepatic or systemic disease, no history of gastric or choledochal surgery (except cholecystectomy), no active pancreatitis, no previous sphincterotomy, no biliary stricture, no choledochal cyst, no addiction. Exclusion criteria: precut sphincterotomy, failure of cannulation of common hepatic duct, no stone in endoscopic retrograde cholangiopancreatography, lack of consent to cooperate in trial.

Age

From **16 years** old to **90 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study is single-blind because participants will be deliberately kept ignorant of either the group to which they will be assigned, but the experimenter will be in possession of the ballooning time in each one. Patients will be randomly assigned to one of the two groups by using a table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research, Isfahan University of Medical Sciences and Health Services

Street address

Building No.4, Isfahan University of Medical Sciences and Health Services, Hezarjarib Street, Isfahan

City

Isfahan

Postal code

8174673461

Approval date

2013-04-03, 1392/01/14

Ethics committee reference number

392004

Health conditions studied

1

Description of health condition studied

Choleducolithiasis

ICD-10 code

K80.5

ICD-10 code description

Calculus of bile duct without cholangitis or cholecystitis

Primary outcomes

1

Description

Common Bile Duct stone clearance

Timepoint

Just after the intervention

Method of measurement

Observation (stone or stones extraction)

Secondary outcomes

1

Description

Abdominal pain

Timepoint

Every six hours up to 48 hours after the intervention

Method of measurement

History and physical examination

2

Description

Fever

Timepoint

Every six hours up to 48 hours after the intervention

Method of measurement

Oral thermometer, temperature equal or more than 38 degree of Celsius

3

Description

Serum amylase level

Timepoint

Before and 2 hours after the intervention

Method of measurement

ELISA kits: International Unit per Litre

4

Description

Hemorrhage

Timepoint

Every six hours up to 48 hours after the intervention

Method of measurement

History and physical examination

5

Description

Perforation

Timepoint

Every six hours up to 48 hours after the intervention

Method of measurement

History and physical examination

6

Description

Pancreatitis

Timepoint

Every six hours up to 24 hours after the intervention

Method of measurement

History, physical examination and serum amylase 2 hours after the procedure

Intervention groups

1

Description

After endoscopic retrograde cholangiopancreatography, minimal papillary sphincterotomy up to proximal fold will perform with sphincterotomy and electrocautery (blended current, 40-60 W). Then papillary balloon will be dilated with Trans The Scope Balloon (Cook medical Hercules® 3 Stage BalloonG31926, HBD-12-13.5-15) for five seconds. Then stone or stones will be retrieved with balloon extractor.

Category

Treatment - Surgery

2

Description

After endoscopic retrograde cholangiopancreatography, minimal papillary sphincterotomy up to proximal fold will perform with sphincterotomy and electrocautery (blended current, 40-60 W). Then papillary balloon will be dilated with Trans The Scope Balloon (Cook medical Hercules® 3 Stage BalloonG31926, HBD-12-13.5-15) for one minute. Then stone or stones will be retrieved with balloon extractor.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital, Endoscopy Department

Full name of responsible person

Mohammad Hadi Shafigh Ardestani

Street address

Al-Zahra Hospital, Soffeh Blvd., Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences and Health Services

Full name of responsible person

Peyman Adibi

Street address

Building No.4, Isfahan University of Medical Sciences and Health Services, Hezarjarib Street, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences and Health Services

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

Isfahan University of Medical Sciences and Health Services

Full name of responsible person

Mohammad Hadi Shafigh Ardestani

Position

Fellowship of Gastroenterology

Other areas of specialty/work

Street address

Gastroenterology Department, Al-Zahra Hospital, Soffeh Blvd., Isfahan

City

Isfahan

Postal code

Phone

+98 31 1668 5555

Fax

+98 31 1668 4510

Email

mhshafigh@resident.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences and Health Services

Full name of responsible person

Ahmad Shavakhi

Position

Associate Professor of Gastroenterology

Other areas of specialty/work

Street address

Gastroenterology Department, Al-Zahra Hospital, Soffeh Blvd., Isfahan

City

Isfahan

Postal code

Phone

+98 31 1668 5555

Fax

Email

shavakhi@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences and Health Services

Full name of responsible person

Mohammad Hadi Shafigh Ardestani

Position

Fellowship of Gastroenterology

Other areas of specialty/work

Street address

Gastroenterology Department, Al-Zahra Hospital, Soffeh Blvd., Isfahan

City

Isfahan

Postal code

Phone

+98 31 1668 5555

Fax

Email

mhshafigh@resident.mui.ac.ir

Web page address

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