

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of endoscopic papillary large balloon dilation with balloon sizes more and less than 15 mm with limited sphincterotomy in management of large common bile duct stones in Taleghani hospital 2017-2018

Protocol summary

Study aim

Comparison of clinical outcomes and complications of endoscopic dilatation balloons between balloons with size more and less than 15 mm

Design

This study is a randomized, single-blind, randomized clinical trial. The first group consists of patients with a balloon dilatation size of more than 15 mm and the second group consists of patients whose balloon size is less than 15 mm.

Settings and conduct

All patients admitted to the gastrointestinal ward of Ayatollah Taleghani Hospital in Tehran who have bile ducts above 15 mm and who are candidates for balloon dilatation with a large balloon will be included in the study. Clinical outcomes and endoscopic effects of balloon dilatation will be compared between balloons above 15 and below 15 mm. Demographic data, clinical data, clinical outcomes of balloon dilatation and complications of the procedure are recorded and compared between the two groups.

Participants/Inclusion and exclusion criteria

Patients with large biliary stones larger than 15 mm in diameter under the balloon dilatation at Tehran Taleghani Hospital enrolled in the study. exclusion criteria include patient dissatisfaction, patients with a history of sphincterotomy, coagulation disorder, renal failure, cirrhosis, bile duct stenosis, biliary dystrophy.

Intervention groups

30 patients were randomly assigned into two groups (the first group was balloon dilatation with a balloon greater than 15 mm and the second group with a balloon less than 15 mm)

Main outcome variables

Demographic data; Clinical information; Clinical outcomes of the balloon dilation; complications from the

procedure; bleeding; probable mortality of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181117041684N1**

Registration date: **2019-08-13, 1398/05/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-13, 1398/05/22**

Update count: **0**

Registration date

2019-08-13, 1398/05/22

Registrant information

Name

parna sadat Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 9614

Email address

parna.hosseini@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of endoscopic papillary large balloon dilation with balloon sizes more and less than 15 mm with limited sphincterotomy in management of large common bile duct stones in Taleghani hospital 2017-2018

Public title

Comparison of endoscopic papillary large balloon dilation in management of large common bile duct stones

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with large biliary stones (with a stone size greater than 15 mm)

Exclusion criteria:

History of sphincterotomy, coagulation disorder, renal failure, cirrhosis, distal stenosis of the biliary duct, biliary diverticulum

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients are not aware that they are less than or equal to 15 mm in the balloon group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid beheshti University of Medical Sciences

Street address

Taleghani hospital, Araabi st, Yaman Ave, Chamran highway, Tehran

City

Tehran

Province

Tehran

Postal code

145678908

Approval date

2019-06-18, 1398/03/28

Ethics committee reference number

IR.SBMU.MSP.REC.1398.294

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

Bile duct stone

ICD-10 code

K83.9

ICD-10 code description

Disease of biliary tract, unspecified

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

The success rate of biliary stone excretion and post-endoscopic complications.

Timepoint

onest of balloon dilation until a day after procedure

Method of measurement

observation of exerted stone and Examination of post-endoscopic complication

Secondary outcomes

empty

Intervention groups**1****Description**

A group of patients treated with a balloon less than 15 mm in size.

Category

Treatment - Devices

2**Description**

A group of patients treated with a balloon more than 15 mm in size.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital Tehran

Full name of responsible person

Parna Sadat Hosseini

Street address

Taleghani hospital,Araabi st,Yaman st,Chamran highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parna Sadat Hosseini

Position

Asistant Student

Latest degree

Medical doctor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the underlying and subsidiary results can be made public without mentioning the patients' names

When the data will become available and for how long

Start one year after the article presentation

To whom data/document is available

Researchers involved in academic centers and research institutes that are researching in related subjects.

Under which criteria data/document could be used

In order to cite sciences in similar studies

From where data/document is obtainable

via E-mail to correspondingc author.

What processes are involved for a request to access data/document

Request by Email-Cheking in study group-response

Comments