Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effect of percutaneous ballooning in the treatment of benign biliary strictures

Protocol summary

Summary

This is an intervention before-after study which investigates the effect of percutaneous biliary balloon dilatation in symptomatic patients suffering from benign biliary strictures. We include Patients in the study if there has been confirmed benign biliary stricture؛ clinical symptoms were present such as icterus, pruritus, in addition to increase in serum bilirubin and liver enzymes. Patients with the following criteria will exclude from the study: any history of malignancies؛ absence patient compliance.Our sample volume is calculated 24. After the confirmation of ethical consequences by ethics committee of the Imam Khomeini hospital; patients have been introduced to the details of the procedure and signed the informed consent forms. Patients asked to stop taking anticoagulant agents 5-7 days prior to scheduled procedure. Percutaneous transhepatic cholangiography will be done and external biliary drainage using a pigtail catheter for a week will insert. After one week, a 40-80 mm length angioplasty balloon using high pressure inflation (20 atmospheres) will insert for 15 minutes in a single session. Follow up session will performed one week later using percutaneous transhepatic cholangiography. The dilatation session will repeat if remained stricture would be visible in percutaneous transhepatic cholangiography. Follow-ups in 3 and 6 months later will be done if the duct would be patent in percutaneous transhepatic cholangiography. Serum Bilirubin level, liver enzymes level and ultrasonography findings will investigate in every follow-up session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406247435N2**
Registration date: **2014-11-28, 1393/09/07**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-11-28, 1393/09/07

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-11-01, 1391/08/11

Expected recruitment end date

2014-12-30, 1393/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of percutaneous ballooning in the treatment of benign biliary strictures

Public title

Evaluation of the effect of percutaneous ballooning in the treatment of benign biliary strictures

Purpose

Treatment

Inclusion/Exclusion criteria
inclusion criteria: benign biliary stricture diagnosed by sonography; cholestatic symptoms exclusion criteria: malignant stricture; patient disability; patient dissatisfaction
Age
From **20 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences Research Faculty
Street address
Tehran University of Medical Sciences
City
Tehran
Postal code
Approval date
2012-10-23, 1391/08/02
Ethics committee reference number
91-02-98-237-63-191

Health conditions studied

1

Description of health condition studied
benign billiary stricture
ICD-10 code
K83.1
ICD-10 code description
Obstruction of bile duct Occlusion Stenosis Stricture of bile duct without calculus

Primary outcomes

1

Description
Releaving of billiary stenosis
Timepoint
Before and after intervention
Method of measurement
Cholangiography

Secondary outcomes

1

Description
Cholestatic symptoms
Timepoint
Before and after and 6 month after intervention
Method of measurement
Interview

2

Description
Total billirubin
Timepoint
Before and after and 6 month after intervention
Method of measurement
Blood test

Intervention groups

1

Description
percutaneus balloon dilation In this procedure ballon holded catheter inserts bile ducts percotaneously. when ballon placed in proper site of stricture, dilatation is done. This procedure is performed under chollangiography guide. There is not control group in this study
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeni Hospital Imaging Center
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University 0f Medical Science
Full name of responsible person
Hazhir Saberi
Street address
Imam Khomeni Hospital Imaging Center
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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
Tehran University 0f Medical Science
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
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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