

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Examination and treatment of bile duct strictures following biliary anastomosis in patients referred to Ghaem (Aj) and Imam Reza (A) hospitals.

Protocol summary

Study aim

Eliminating the symptoms of fever, chills and jaundice in patients with a history of hepatojejunostomy surgery

Design

All patients who underwent biliary anastomosis surgery in the form of hepatojejunostomy were included in the study. At this stage, informed consent was again obtained from patients who had strictures due to malignancy, or had a history of taking immunosuppressive drugs, or had complete obstruction of the bile ducts. Patients who had symptoms of icterus, fever, chills and symptoms of cholangitis and suspected anastomotic stenosis and were confirmed by ultrasound and MRCP were included in the study, they were subjected to endoscopic surgery and enterotomy was performed, and then with a urological nephroscope, which has a working port, we enter the lumen of the intestine and determine the location of the anastomosis, and then widen the anastomotic stricture with a dilator. and if there is a stone before the anastomosis, we remove the stone by washing and using a special tool.

Settings and conduct

In two educational, research and medical centers of Qaem Hospital (Aj) and Imam Reza Hospital, which have a general surgery department and laparoscopy facilities.

Participants/Inclusion and exclusion criteria

Patients with symptoms of biliary strictures who have already undergone surgery

Intervention groups

Patients with symptoms of biliary strictures who have undergone endoscopic surgery

Main outcome variables

Patients who underwent biliary anastomosis surgery as hepatojejunostomy were included in the study. At this stage, informed consent was again obtained from the patients. The patients who had symptoms of jaundice,

fever, chills, and symptoms of cholangitis, and suspected anastomotic stenosis and were confirmed by ultrasound and mrCP, were excluded from the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090826002373N2**

Registration date: **2022-07-10, 1401/04/19**

Registration timing: **prospective**

Last update: **2022-07-10, 1401/04/19**

Update count: **0**

Registration date

2022-07-10, 1401/04/19

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

8012806-8012841

Email address

tavassolia@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-01, 1401/05/10

Expected recruitment end date

2022-11-01, 1401/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Examination and treatment of bile duct strictures following biliary anastomosis in patients referred to Ghaem (Aj) and Imam Reza (A) hospitals.

Public title
Discussion and Treatment Icter

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
History of surgery
Exclusion criteria:
Jaundice due to complete obstruction of the bile ducts

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **7**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Park square, Mashhad University of Medical Sciences
City
mashhad
Province
Razavi Khorasan
Postal code
3316-913791
Approval date
2022-06-13, 1401/03/23

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.171

Health conditions studied

1

Description of health condition studied

Icter

ICD-10 code

K83.1

ICD-10 code description

Obstruction of bile duct

Primary outcomes

1

Description

Eliminate the symptoms of fever, chills and jaundice

Timepoint

Liver function test (LFT) with 30 day

Method of measurement

Liver function test (LFT)

Secondary outcomes

empty

Intervention groups

1

Description

Patients with symptoms of biliary strictures who underwent endoscopic surgery. 7 patients underwent minimally invasive surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Qhaem hospital

Full name of responsible person

Dr Tavakkoli

Street address

Ahmad abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

3316-913791

Phone

+98 915 310 1013

Email

tavakkoliri971@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Iman Tavakkoli

Street address

Ahmadabad Ave ghaem hospital

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Grant name

Grant code / Reference number

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

No

Title of funding source

Mashhad university

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

Mashhad University of Medical Sciences

Full name of responsible person

Iman Tavakkoli

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

Street address

Ahmad abad Ave,ghaem hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Alireza Tavassoli

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

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Person responsible for updating data

Contact

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Full name of responsible person

Alireza Tavassoli

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No information about that

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available

Title and more details about the data/document

All data can be shared after de-identification.

When the data will become available and for how long
Access starts 6 months after the study

To whom data/document is available
The data is accessible to all.

Under which criteria data/document could be used
Those who work in the same field.

From where data/document is obtainable
Dr Tavakkoli

What processes are involved for a request to access data/document
tavakkoliri971@mums.ac.ir

Comments