Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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. were excluded from the study 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 squere,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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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
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Iman Tavakkoli
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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