Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the efficacy of prophylactic pancreatic duct stenting in the prevention of post-ERCP-pancreatitis in patients with difficult common bile duct cannulation using double guide wire technique

Protocol summary

Study aim

Investigating the effect of prophylactic pancreatic duct stenting in preventing pancreatitis after ERCP and comparing it with the group that did not undergo stenting.

Design

A clinical trial with two parallel groups, one side blind and on 238 patients, the trial phase is not applicable for this study. Randomization based on random blocks

Settings and conduct

All patients who are referred to Taleghani Hospital in Tehran for the first time for ERCP and who meet the criteria for difficult biliary cannulation and who have experienced at least one unintentional PD cannulation will be included in this study. The degree of difficulty of biliary cannulation is graded as grade 1 for easy cannulation, grade 2 for cannulation with moderate difficulty, and grade 3 for difficult cannulation. Patients with grade 2 and 3 difficult cannulation are subjected to biliary drainage techniques including DGW, TPS and OGW. Then, they are randomly targeted in the PDS inclusion or non-implementation experiment. A Boston Scientific 5cm-5Fr pigtail stent will be placed in all PD stenting candidates. Finally, patients will be followed for improvement of symptoms and occurrence of side effects during hospitalization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients suspected of acute biliary pancreatitis, biochemical findings and ultrasound findings. Exclusion criteria: cardiopulmonary disease and other systemic diseases that endanger anesthesia

Intervention groups

In the first group (intervention), prophylactic bile duct stents will be implanted for patients. In the second group (control), patients will not be placed under the bile duct stent.

Main outcome variables

Cannulation success rate; Complications include pancreatitis, perforation, bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230314057717N3**
Registration date: **2023-07-05, 1402/04/14**
Registration timing: **prospective**

Last update: **2023-07-05, 1402/04/14**
Update count: **0**

Registration date

2023-07-05, 1402/04/14

Registrant information

Name

Amir Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the efficacy of prophylactic pancreatic duct stenting in the prevention of post-ERCP-pancreatitis in patients with difficult common bile duct cannulation using double guide wire technique

Public title

Investigating the effect of pancreatic duct stent in the prevention of pancreatitis after ERCP

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with acute pancreatitis (increased amylase and lipase 3 times more than normal) Patients with gallstones on ultrasound suspected to have CBD stones (symptomatic gallstone disease) Biochemical findings (increased AST, ALP, ALT or bilirubin) Ultrasound findings (diagnosis of stones or enlargement of the CBD) that indicate a CBD stone or blockage of the CBD

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **238**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to two groups using the random block method. The number of blocks will be 4 and in each block three patients will be included in the study order. Random allocation of blocks of patients to two treatment groups will be done through Sealed Envelope online software. The randomized list of blocks is placed in sealed envelopes and will be provided to the endoscopist on a daily basis

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to avoid the bias of the analyst, he does not know which patient is in which group, and the patients' characteristics are provided to him in a coded form.

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 Faculty of Medicine

Street address

Arabi street, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717413

Approval date

2022-09-20, 1401/06/29

Ethics committee reference number

IR.SBMU.MSP.REC.1401.308

Health conditions studied

1

Description of health condition studied

Bile duct disease

ICD-10 code

K83.1

ICD-10 code description

Obstruction of bile duct

Primary outcomes

1

Description

Incidence of pancreatitis after ERCP

Timepoint

6 hours after the procedure

Method of measurement

Blood Amylase and/or lipase 3 times higher than normal 24 hours after the procedure with abdominal pain

2

Description

Success rate of bile duct cannulation

Timepoint

At the time of cannulation by the endoscopist

Method of measurement

Visual diagnosis of the endoscopist by observing the cannulation process on the monitor

3

Description

Bleeding

Timepoint

During or after the procedure

Method of measurement

Clinical evidence of bleeding or hemoglobin drop

4

Description
Perforation of bile duct
Timepoint
During the procedure
Method of measurement
Clinical evidence of perforation of the lateral or medial wall of the bile duct

5

Description
Cholangitis
Timepoint
6 hours after the procedure
Method of measurement
When the bile duct becomes infected (abdominal pain and fever over 38 degrees)

Secondary outcomes

1

Description
Body temperature
Timepoint
4 hours after the completion of the procedure
Method of measurement
Thermometer

2

Description
Amylas
Timepoint
before the procedure and 3 hours after the procedure
Method of measurement
Blood test

3

Description
Lipas
Timepoint
before the procedure and 3 hours after the procedure
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Patients who undergo implantation of a 5cm-5Fr pigtail Boston Scientific stent in the pancreatic duct.
Category
Treatment - Devices

2

Description
Control group: Patients who do not undergo bile duct stenting
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Amir Sadeghi
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Arabi street, Velenjak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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

Gholamreza Noori

Position

Gastroenterologist assistant

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

The statistical analysis plan, study design and information on main outcomes will be shared

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Researchers, medical students, professors and doctors

Under which criteria data/document could be used

If used for further research and in compliance with the principle of referencing

From where data/document is obtainable

Responsible author Amir Sadeghi amirsadeghimd@yahoo.com

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

Send the request to the responsible author and outline the reason for the request

Comments