

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of two technical methods of fistulotomy over a pancreatic guide-wire and trans-pancreatic sphincterotomy in difficult cases of ERCP with advertent or inadvertent PD cannulation

Protocol summary

Study aim

Comparison of two bile duct cannulation methods in difficult ERCP cases with advertent or inadvertent pancreatic cannulation.

Design

Clinical trial with two parallel groups, double-blind and on 200 patients, trial phase is not applicable for this study. Randomization based on random blocks

Settings and conduct

ERCP candidate patients referred to Taleghani Hospital in Tehran, whose bile duct cannulation is difficult, are included in the study. One group is cannulated with fistulotomy over the pancreatic guidewire. The second group is cannulated with transpancreatic sphincterotomy technique. After the procedure, the patients will be evaluated in terms of complications and success rate of cannulation. The study is double-blind, so that the necessary information is provided to the patients regarding the study, it will be stated that there are two types of methods for their ERCP, but they will not know in which group and by which method they will undergo cannulation. Also, the data analyst does not know how to assign groups and results

Participants/Inclusion and exclusion criteria

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

Intervention groups

In group 1, the bile duct will be cannulated with the fistulotomy over the PD guidewire. First, a stent will be placed in the duct of the pancreas. Then, the guidewire passes through the stent and enters the bile duct through the pancreas. In group 2, the bile duct will be cannulated with the trans pancreatic fistulotomy technique. The endoscopist enters the pancreas with a guide wire and enters the bile duct by creating a hole in

the pancreas.

Main outcome variables

cannulation success rate; Complications include pancreatitis, perforation, bleeding

General information

Reason for update

Acronym

ERCP

IRCT registration information

IRCT registration number: **IRCT20230314057717N1**

Registration date: **2023-04-15, 1402/01/26**

Registration timing: **prospective**

Last update: **2023-04-15, 1402/01/26**

Update count: **0**

Registration date

2023-04-15, 1402/01/26

Registrant information

Name

Amir Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2540

Email address

amirsadaghi@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two technical methods of fistulotomy over a pancreatic guide-wire and trans-pancreatic sphincterotomy in difficult cases of ERCP with advertent or inadvertent PD cannulation

Public title

Review of the least complicated technique of bile duct cannulation in difficult ERCP cases

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:

Patients with severe coagulopathy or previous Roux-en-y gastric surgery Gastrostomy pregnancy Contrast sensitivity History of previous sphincterotomy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyst

Sample size

Target sample size: **200**

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 each block will have three patients based on the order of entry are studied. Random allocation of blocks of patients to two treatment groups It will be done through Sealed Envelope online software. Randomized list The blocks are placed in sealed envelopes and will be provided to the endoscopist daily

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients who are in each group do not know about which biliary duct cannulation method they have been placed in. Also, in order to avoid the bias of the analyst, he is not aware of the allocation of the study groups and the data is provided to him in the form of code.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Gastroenterology and Liver Research Institute of Shahid Beheshti University of M

Street address

arabi street, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717413

Approval date

2023-03-11, 1401/12/20

Ethics committee reference number

IR.SBMU.RIGLD.REC.1401.038

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

Obstruction of the bile ducts

ICD-10 code

K83.1

ICD-10 code description

Obstruction of bile duct

Primary outcomes**1****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

2**Description**

Bleeding

Timepoint

during or after the procedure

Method of measurement

Clinical evidence of bleeding or hemoglobin drop

3

Description

pancreatic

Timepoint

6 hours after the procedure

Method of measurement

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

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

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 (CBC)

3

Description

lipas

Timepoint

before the procedure and 3 hours after the procedure

Method of measurement

blood test (CBC)

Intervention groups

1

Description

Intervention group: In the first group, the bile duct of the patients will be cannulated with the fistulotomy over the pancreatic guidewire technique. Patients will undergo ERCP in one session and its duration will be between 20 and 60 minutes depending on the difficulty of cannulation. First, a stent will be inserted in the duct of the patient's pancreas. The guidewire will then pass over the stent, and through the pancreas, into the bile duct.

Category

Treatment - Other

2

Description

Intervention group: In the second group, the bile duct of the patients will be cannulated with the trans pancreatic fistulotomy technique. Patients will undergo ERCP in one session and its duration will be between 20 and 60 minutes depending on the difficulty of cannulation. In this method, the endoscopist enters the pancreas with a guide wire and enters the bile duct by creating a hole in the pancreas.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Taleghani Hospital

Full name of responsible person

Amir Sadeghi

Street address

Arabi street, Velenjak

City

Tehran

Province

Tehran

Postal code

3816149369

Phone

+98 912 501 6596

Email

amirsadeghimd@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Arabi street, velenjak

City

Tehran
Province
Tehran
Postal code
32776063
Phone
+98 21 3277 6063
Email
zarghi@sbmu.ac.ir
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
Ehsan Hosein zadeh
Position
Gastroenterologist assistant
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Arabi street, Velenjak
City
Tehran
Province
Tehran
Postal code
3816149369
Phone
+98 21 2243 2540
Email
hosseinzadehehsan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Amir Sadeghi

Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Arabi street, Velenjak
City
Tehran
Province
Tehran
Postal code
3816149369
Phone
+98 21 2243 2540
Email
amirsadeghimd@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ehsan Hoseinzadeh
Position
Assistant gastroenterology specialist
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Arabi street, velenjak
City
Tehran
Province
Tehran
Postal code
3816149369
Phone
+98 21 2243 2540
Email
hosseinzadehehsan@yahoo.com

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

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 publishing 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

corresponding 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