Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 snephcterotomy 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@sbmu.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 Gastrogenostomy pregnancy Contrast sensitivity History of previous sphincterotomy
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

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