Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two preincisional sphincterotomy methods, needle knife fistulotomy versus transpancreatic sphincterotomy as path-breaking treatments in difficult ERCP conditions: a randomized controlled trial

Protocol summary

Study aim

Comparing the success rate of pre-cut fistulotomy and TPS in patients with difficult ERCP

Design

This study was conducted on 128 ERCP candidate patients. Patients with difficult ERCP were divided into two intervention groups based on randomization of numbers and underwent the procedure. Then, information such as endoscopy findings, the final success rate of cannulation and the side effects of each method were recorded. Finally, by following up the clinical condition of the patients and blood tests such as the level of hemoglobin, amylase and serum lipase and bilirubin, the success rate was determined as the primary outcome and side effects. Patients were recorded as a secondary outcome. After ERCP, the patients were observed and checked for side effects such as pancreatitis, bleeding, perforation and cholangitis. double-blind manner.

Settings and conduct

It was done on ERCP candidate patients in the endoscopy ward of Taleghani Hospital. In one group, they underwent fistulotomy by cannulation with a needle knife above the papillary orifice, and one group underwent transpancreatic sphincterotomy. The design is double-blind, and the patients and the analyst are unaware of the allocation of groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: acute pancreatitis; gallstones in ultrasound suspected of CBD stones and biochemical findings and ultrasound findings suggestive of CBD stones or CBD obstruction. Exclusion conditions: severe coagulopathy or previous gastric surgery with Roux-en-y; gastrojejunostomy; sensitivity to contrast material; previous history of sphincterotomy.

Intervention groups

Group A: patients who underwent fistulotomy with a needle knife above the papillary opening and then standard papillotomy. Group B: patients underwent transpancreatic sphincterotomy and then standard papillotomy.

Main outcome variables

Cannulation success and complication rate

General information

Reason for update

Acronym

ERCP

IRCT registration information

IRCT registration number: **IRCT20220905055884N1**
Registration date: **2022-10-05, 1401/07/13**
Registration timing: **retrospective**

Last update: **2022-10-05, 1401/07/13**
Update count: **0**

Registration date

2022-10-05, 1401/07/13

Registrant information

Name

hamid Asadzadeh aghdaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date
2022-06-22, 1401/04/01
Actual recruitment start date
2022-04-04, 1401/01/15
Actual recruitment end date
2022-08-21, 1401/05/30
Trial completion date
2022-08-21, 1401/05/30

Scientific title
Comparison of two preincisional sphincterotomy methods, needle knife fistulotomy versus transpancreatic sphincterotomy as path-breaking treatments in difficult ERCP conditions: a randomized controlled trial

Public title
Comparison of two bile duct cannulation methods in difficult ERCP cases
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People more than 18 years old Patients with acute pancreatitis (elevation of Amylase and Lipase more than 3-fold the upper limit of normal) suspicious of Acute biliary pancreatitis Patients with gallstone in ultrasound suspicious of CBD stone (symptomatic gallstone disease) Biochemical (elevation of AST, ALT, ALP and/or bilirubin) and ultrasound findings (stone detection and/or CBD dilation) indicating CBD stone or CBD obstruction
Exclusion criteria:
Patients with severe coagulopathy or previous gastric surgery with Roux_en_y Gastrojejunostomy Pregnancy Sensitivity to contrast material Sensitivity to contrast material
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **128**
Actual sample size reached: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization method: In simple random sampling, each patient has an equal chance of being selected to be in one of the groups. In this study, patients were randomly selected and placed in the group of cannulation with pre cut sphincterotomy or cannulation with transpancreatic sphincterotomy.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients who are in each group do not know about which bile duct cannulation method they have undergone, also in order to prevent abuse by the analyzing person, he is unaware of the allocation of study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of gastrointestinal research institute Shahid Beheshti University of Medical Scienc
Street address
Gastrointestinal and liver disease research center, Arabi street, Velenjak
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-03-08, 1400/12/17
Ethics committee reference number
IR.SBMU.MSP.REC.1400.807

Health conditions studied

1

Description of health condition studied
Obstruction of bile duct
ICD-10 code
K83.1
ICD-10 code description
Obstruction of bile duct

Primary outcomes

1

Description
Temperature
Timepoint
Before and after the procedure
Method of measurement
Body temperature measuring tool

2

Description
Complete blood count (CBC) differentiation
Timepoint

Before and after the procedure
Method of measurement
Blood test

3

Description
Amylas
Timepoint
Before and after the procedure
Method of measurement
Blood test

4

Description
Lipase
Timepoint
Before and after the procedure
Method of measurement
Blood test

5

Description
Post ERCP bleeding
Timepoint
During or after the procedure
Method of measurement
Clinical evidence of bleeding with hemoglobin drop

6

Description
Post ERCP Pancreatitis
Timepoint
6 hours after the procedure
Method of measurement
Amylase at least 3 times normal more than 24 hours after the procedure with abdominal pain

7

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

8

Description
Cholangitis
Timepoint
6 hours after ERCP
Method of measurement
When the bile duct become infected(RUQ pain, T>38)

Secondary outcomes

1

Description
Timepoint
Method of measurement

Intervention groups

1

Description
Intervention group: Patients who underwent fistulotomy with a needle knife above the papillary opening and then bile duct cannulation.
Category
Treatment - Other

2

Description
Intervention group: Patients underwent Trans-pancreatic precut sphincterotomy followed by bile duct cannulation.
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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Taleghani hospital, Arabi street, Velenjak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Azam Farahani
Position
sub-Specialist assistant
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Person responsible for updating data

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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
Privacy and confidentiality
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 paper

To whom data/document is available

Researchers, 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

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