# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

23 Jun 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**

Shahid Beheshti 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?**
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
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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**