

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Efficacy and safety of primary Needle Knife Fistulotomy in patients undergoing ERCP with a long papilla: A single blind randomized prospective study

Protocol summary

Study aim

Investigating the efficacy and safety of two fistulotomy techniques with the primary needle knife compared to the standard technique in patients undergoing ERCP with long papillae

Design

Clinical trial with parallel groups, single blind, randomized, sample size 181 patients, Excel software was used for randomization.

Settings and conduct

In the endoscopy department of Taleghani Hospital, patients with indications for ERCP with large papilla are randomly divided into two groups with a blinding strain. Patients are blinded to the type of intervention and the researcher in the study. For the first group, bile duct cannulation will be done with the basic needle knife method. For the second group, patients undergo cannulation with a standard method. After the procedure, the success rate of each of the methods as well as the rate of complications after that will be evaluated.

Participants/Inclusion and exclusion criteria

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

Intervention groups

Candidates for ERCP with large papillae are randomly divided into two groups. The first group of bile duct cannulation with the basic needle knife method and the second group of patients are subjected to cannulation with the standard method.

Main outcome variables

cannulation success rate; Complications include pancreatitis, perforation, bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221026056313N1**

Registration date: **2023-07-24, 1402/05/02**

Registration timing: **prospective**

Last update: **2023-07-24, 1402/05/02**

Update count: **0**

Registration date

2023-07-24, 1402/05/02

Registrant information

Name

mehrnoosh alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2560

Email address

mehrnoosh_alizadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

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

Efficacy and safety of primary Needle Knife Fistulotomy in patients undergoing ERCP with a long papilla: A single blind randomized prospective study

Public title

Efficacy and safety of primary Needle Knife Fistulotomy in patients undergoing ERCP with a long papilla

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People over 18 years old Patients with acute pancreatitis Patients with gallstones ultrasound findings (CBD dilatation) that indicate CBD stone and CBD obstruction.

Exclusion criteria:

Age less than 18 years pregnancy Contrast sensitivity History of previous sphincterectomy Refusal to give informed written consent Gastrojejunostomy Patients with severe coagulopathy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **181**

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

The study will be done in a blind way. The evaluator does not know how to assign patients to the group in order to prevent misuse in measuring the results of the study.

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

Street address

Yemen St., Shahid Arabi St., Ayatollah Taleghani Hospital

City

Tehran

Province

Tehran

Postal code

1985717413

Approval date

2023-06-03, 1402/03/13

Ethics committee reference number

IR.SBMU.MSP.REC.1402.098

Health conditions studied

1

Description of health condition studied

bile duct disorder

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

post ERCP complication

Timepoint

During or after the procedure

Method of measurement

Clinical evidence and laboratory tests of bleeding, perforation, pancreatitis

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 for investigation of Amylas level

3

Description

lipas

Timepoint

before the procedure and 3 hours after the procedure

Method of measurement

blood test for investigation of lipas level

Intervention groups

1

Description

Intervention group: Intervention group: In the first group, the bile ducts of the patients will be cannulated with a standard technique. In this technique, the guidewire enters the bile duct through the papilla. Patients will undergo ERCP in one session, and its duration will be between 20 and 60 minutes, depending on the difficulty of cannulation.

Category

Other

2

Description

Intervention group: In the second group, entry into the bile duct will be done with the basic needle-knife technique. In this technique, first an incision is made above the papilla hole, and then the guidewire will enter the bile duct through this incision. Patients will undergo ERCP in one session, and its duration will be between 20 and 60 minutes depending on the difficulty of cannulation.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Mehrnoosh Alizadeh

Street address

Yemen St., Shahid Arabi St., Ayatollah Taleghani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin zarghi

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Shahid Beheshti University of Medical Sciences, El Arabi St., Valenjak

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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

Mehrnoosh alizadeh

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Position

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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

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable