Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Cryoprevention Combined with Rectal Diclofenac Suppository Versus Rectal Diclofenac Alone in the Prevention of Post-ERCP Pancreatitis

Protocol summary

Study aim

The main objective of this study is to investigate the synergistic effect of cryoprevention combined with rectal diclofenac suppository versus rectal diclofenac alone in the prevention of post-endoscopic retrograde cholangiopancreatography pancreatitis

Design

Randomized controlled trial with parallel groups, involving blinding of the patient, outcome assessor, and statistician on one hundred patients

Settings and conduct

This study is conducted at Imam Reza Hospital, affiliated with Tabriz University of Medical Sciences. Eligible patients are randomly allocated into an intervention group receiving cold water infusion with rectal diclofenac and a control group receiving rectal diclofenac alone. This study is performed as a triple-blind trial involving blinding of the patient, outcome assessor, and statistician.

Participants/Inclusion and exclusion criteria

nclusion Criteria: - Age ≥18 years - Native papilla - No NSAID contraindications - Written informed consent Exclusion Criteria: - Need for prophylactic pancreatic stenting - Failed ERCP - Pre-existing pancreatitis - Pancreatic cancer or cholangiocarcinoma - Acute or chronic pancreatitis

Intervention groups

ntervention Group: After successful cannulation, 250 mL of 4°C cold water is infused into the papilla, and 100 mg rectal diclofenac is administered before ERCP. Control Group: Patients receive 100 mg rectal diclofenac before ERCP, without cold water infusion.

Main outcome variables

The occurrence of pancreatitis is evaluated based on clinical criteria and abdominal symptoms. Furthermore, the magnitude of changes and elevation in serum levels of amylase and lipase enzymes are measured and assessed twenty-four hours after the procedure.

General information

Reason for update

Acronym

CAD-PEP

IRCT registration information

IRCT registration number: **IRCT20261012071401N1**
Registration date: **2026-10-16, 1405/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-16, 1405/07/24**
Update count: **0**

Registration date

2026-10-16, 1405/07/24

Registrant information

Name

javad Ghadimi haji agha

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-03-21, 1405/01/01

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cryoprevention Combined with Rectal Diclofenac Suppository Versus Rectal Diclofenac Alone in the Prevention of Post-ERCP Pancreatitis

Public title

Synergistic Effects of Cryoprevention and Rectal Diclofenac on the Prevention of Post-ERCP Pancreatiti

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a native papilla (no history of prior manipulation) Absence of contraindications to NSAID use (active peptic ulcer disease, GFR<30 mL/min/1.73m2GFR<30 mL/min/1.73m2, known hypersensitivity to NSAIDs, or recent gastrointestinal bleeding) Written informed consent for participation in the study

Exclusion criteria:

Requirement for prophylactic pancreatic stent placement Unsuccessful ERCP procedure Pre-existing pancreatitis prior to ERCP Patients diagnosed with pancreatic cancer or cholangiocarcinoma Patients with acute or chronic pancreatitis

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Given the nature of the intervention under investigation—namely, papillary irrigation with cold water during ERCP—blinding of the performing endoscopist is not feasible. However, to minimize potential bias, blinding will be implemented for the patients, outcome assessor, and statistical analyst. Patients will remain blinded to their assigned group due to undergoing the procedure under sedation and lacking awareness of the procedural details during ERCP. Furthermore, information regarding the treatment allocation will not be disclosed to the patient after the procedure. The primary outcome of the study—the incidence of post-ERCP pancreatitis (PEP)—will be evaluated by an independent individual who has no role in the procedure or group allocation and is blinded to the intervention type. The diagnosis of PEP will be established based on predefined clinical and laboratory criteria. To maintain blinding of the statistical analysis, the study groups will be recorded in the data file as codes A and B, and the statistician will remain unaware of the intervention nature of each group until the completion of the analysis. Unblinding will be performed only after the final analysis is completed. Therefore, this study will be conducted as a randomized controlled trial with blinded patients, a blinded outcome assessor, and a blinded statistician.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Deputy of Research and Technology, Central Building, Tabriz University of Medical Sciences, University Street, Tabriz, Iran

City

tabriz

Province

East Azarbaijan

Postal code

۵۱۶۶۶۱۴۷۱۱

Approval date

2026-10-12, 1405/07/20

Ethics committee reference number

IR.TBZMED.REC.1405.499

Health conditions studied

1

Description of health condition studied

Post-ERCP Pancreatitis

ICD-10 code

K85.8

ICD-10 code description

Other acute pancreatitis

Primary outcomes

1

Description

Incidence of post-ERCP pancreatitis (defined as new-

onset upper abdominal pain characteristic of pancreatitis accompanied by an increase in serum amylase or lipase to at least 3 times the upper limit of normal within 24 hours after the procedure)

Timepoint

Measurement of serum amylase and lipase levels and clinical evaluation for typical abdominal pain symptoms at baseline (prior to the ERCP procedure), and subsequently at 24 hours post-ERCP procedure

Method of measurement

Measurement of serum amylase and lipase levels via venous blood sampling using standard laboratory kits and an automated clinical chemistry analyzer, combined with thorough clinical examination by a physician to assess typical abdominal pain consistent with standard diagnostic criteria for acute pancreatitis

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients in this group receive only the standard care for the prevention of post-procedural pancreatitis. Specifically, prior to the endoscopic retrograde cholangiopancreatography procedure, a 100 mg diclofenac sodium suppository (manufactured by a reputable domestic pharmaceutical company) is administered rectally to the patient. No cryoprevention intervention or local cold-water irrigation will be performed for this group, and subsequent care will be provided according to the standard ward protocol.

Category

Prevention

2

Description

Intervention group: Patients in this group receive a combined intervention. Prior to the endoscopic retrograde cholangiopancreatography procedure, a 100 mg diclofenac sodium suppository (manufactured by a reputable domestic pharmaceutical company) is administered rectally to the patient. Furthermore, following successful biliary cannulation and at the end of the procedure, a cryoprevention intervention (local cold therapy of the papillary region) is performed; specifically, 250 cc of cold water (at a standard temperature of 4 degrees Celsius) is locally and controllably infused/irrigated through the scope into the ampulla of Vater and the surrounding papillary area to exert a cooling and anti-inflammatory effect. Subsequent care is continued according to the standard ward protocol.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

emam reza hospital

Full name of responsible person

جواد قدیمی

Street address

Imam Reza Hospital, adjacent to Tabriz University of Medical Sciences, Tabriz, East Azerbaijan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz 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

Tabriz 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
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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
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
The Effect of Cryoprevention Combined with Rectal Diclofenac versus Rectal Diclofenac Alone in Preventing Post-ERCP Pancreatitis
When the data will become available and for how long
Access Period Start: 1406 (2027)
To whom data/document is available
Researchers and Physicians
Under which criteria data/document could be used
Prevention of Post-ERCP Pancreatitis
From where data/document is obtainable
dr.javad ghadimi / javadghh@gmail.com
What processes are involved for a request to access data/document
send email
Comments