Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of rectal diclofenac on prevention of pancreatitis after ERCP (Endoscopic Retrograde Cholangio_ Pancreatography) in comparison with control group

Protocol summary

Study aim
Effect of rectal diclofenac on prevention of pancreatitis after ERCP (Endoscopic Retrograde Cholangio_ Pancreatography) in comparison with control group

Design
Clinical trial with intervention and control groups, double blind, randomized, phase three. Randomization: Random block A, B. Randomization Unit: Individual. Randomization tool: random number table. The operating physician, assistant and patient will not be aware of content of block. Sample size: 75 patients in control group and 75 patients in intervention group.

Settings and conduct
Participants will be randomly divided into two groups of patients and controls. The operating physician, assistant, and patient will not be aware of content of blocks (double blind). Randomly block A, B, individual randomization unit, table randomization tool. The endoscopy unit of Firoozgar Hospital will be located in Tehran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years ; Ability to sign consent ; Intact papillae ; No contraindication for diclofenac ; Having an ERCP indication ; Non-inclusion: Sphincterotomy ; Acute pancreatitis ; Basic amylase above 200 ; Allergy to diclofenac ;

Intervention groups
All patients receive diclofenac suppository before operation.group A(intervention) received diclofenac suppository after ERCP too.

Main outcome variables
Acute pancreatitis after ERCP

General information

Reason for update

Acronym
ERCP (Endoscopic Retrograde Cholangio _pancreatography

IRCT registration information
IRCT registration number: **IRCT20191231045969N2**
Registration date: **2020-09-30, 1399/07/09**
Registration timing: **retrospective**

Last update: **2020-09-30, 1399/07/09**
Update count: **0**

Registration date
2020-09-30, 1399/07/09

Registrant information

Name
Mehdi Nikkhah

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8214 1711

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nikkhah.m@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-09-20, 1399/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of rectal diclofenac on prevention of pancreatitis

after ERCP (Endoscopic Retrograde Cholangio_ Pancreatography) in comparison with control group

Public title
The effect of rectal diclofenac on prevention of pancreatitis after ERCP

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Ability to sign consent Intact papilla No contraindication for diclofenac Having an ERCP indication

Exclusion criteria:
Acute pancreatitis Allergy to diclofenac Sphincterotomy Basic amylase above 200

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to two groups of 75 controls and treatment group. Random allocation of patients will be done using random block method with permutations BA, BA, AB, AB, AA, BB, AB, BA, BA, AB, BB, AA. Thus, for group A, patients will receive diclofenac suppositories immediately before and after ERCP, and for group B, diclofenac suppositories will be given just before ERCP. Participant blinding and outcome assessment will be done single-blind. Since the intervention is performed in patients during anesthesia and patients are blinded in this regard, the study will be conducted blindly due to the lack of placebo. Participants and outcome assessors are not aware of grouping. The patient is explained that he or she may be randomly assigned to groups A and group B. Randomization unit: individual (individuals are assigned to treatment groups) Randomization tool: Random blocking

Blinding (investigator's opinion)
Double blinded

Blinding description
After obtaining the patient's consent, the patient is explained that he / she may accidentally receive diclofenac suppository before and after ERCP in group A and diclofenac suppository before ERCP in group B. Participant blinding and outcome assessment will be done single-blind. Since the intervention is performed on patients during anesthesia, patients will be blinded in this regard, and the study will be conducted blindly due to the lack of placebo. Participants and outcome assessors are not aware of grouping. The patient is explained that he or she may be randomly assigned to groups A and group B. The patient will only be informed of the suppository before performing the ERCP, and after performing the ERCP, the patient will not be informed of whether or not to prescribe the suppository. Only the operating room nurse who distributes the NSAID suppository is aware of the patient's presence in the intervention or control group that they are not involved in the research and will perform the random assignment operation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, next to Milad Tower, Hemat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2020-06-03, 1399/03/14

Ethics committee reference number
IR.IUMS.FMD.REC.1399.190

Health conditions studied

1

Description of health condition studied
Acute pancreatitis

ICD-10 code
Acute panc

ICD-10 code description
K85

Primary outcomes

1

Description
Acute pancreatitis after ERCP

Timepoint
24 hours after ERCP operation

Method of measurement
Examination and testing of lipase amylase

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving two diclofenac rectal suppositories 100 mg, one immediately before ERCP and the other immediately after ERCP.The name of the manufacturer of the consumable material of 100 mg diclofenac rectal suppository is Tehran Pakhsh Company.
Category
Prevention

2

Description
Control group: Patients receiving a 100 mg rectal diclofenac suppository just before ERCP. The name of the company that manufactures the 100 mg diclofenac rectal suppository is Tehran Pakhsh Company.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Mehdi Nikkha
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Firoozgar Hospital, Beh Afarin Street, Vali Asr Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mehdi Nikkhah
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available