

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)

Phone

+98 21 8214 1711

Email address

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

Street address

Firoozgar Hospital, Beh Afarin Street, Vali Asr Square

City

Tehran

Province

Tehran

Postal code

1593748711

Phone

+98 21 8893 7383

Fax

+98 21 8893 7383

Email

agahimahsa@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Abbas Motevalian

Street address

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

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2504

Email

amotevalian@iums.ac.ir

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

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Firoozgar Hospital, Beh Afarin Street, Vali Asr Square

City

Tehran

Province

Tehran

Postal code

1593748711

Phone

+98 21 8893 7383

Email

Nikkhah.m@iums.ac.ir

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

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+98 21 8893 7383

Email

Nikkhah.m@iums.ac.ir

Person responsible for updating data

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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Internal Medicine

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Nikkhah.m@iums.ac.ir

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