Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Effect of Rectal Indomethacin and Nitroglycerin in Comparison with Rectal Indomethacin in the Prevention of post Endoscopic Retrograde Cholangio Pancreatography (ERCP) Pancreatitis

Protocol summary

Study aim
Impact of coadministration of rectal Indomethacin and Sublingual Nitrates in prevention of post ERCP pancreatitis

Design
In this research, 324 eligible patients needed ERCP referring to Qom gastroenterology clinic were chosen purposefully. Then, patients by block randomization were randomly divided into two control and intervention groups.

Settings and conduct
The study was performed as a randomized clinical trial at Shahid Beheshti Hospital in Qom. The study is double-blinded, and intervention is conducted by someone other than the care provider, and care provider and participants is unaware of the type of treatment.

Participants/Inclusion and exclusion criteria
People entering the study aged 18 to 70 years and patients who have contraindication for taking Indomethacin or Nitroglycerin were not included in the study.

Intervention groups
Intervention group: Indomethacin suppository, 100 mg, single dose, before ERCP plus nitroglycerin tablet, 0.4 mg, single sublingual, immediately after ERCP. Control group: Indomethacin suppository, 100 mg, single dose, before ERCP plus placebo tablet, single dose, sublingual, immediately after ERCP

Main outcome variables
Post ERCP pancreatitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161205031252N5**
Registration date: **2018-01-18, 1396/10/28**
Registration timing: **retrospective**

Last update: **2018-01-18, 1396/10/28**
Update count: **0**

Registration date
2018-01-18, 1396/10/28

Registrant information

Name
Ahmad Hormati

Name of organization / entity
Qom university of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-06-25, 1395/04/05

Expected recruitment end date
2016-09-22, 1395/07/01

Actual recruitment start date
2016-06-25, 1395/04/05

Actual recruitment end date
2016-09-22, 1395/07/01

Trial completion date
empty

Scientific title
Effect of Rectal Indomethacin and Nitroglycerin in Comparison with Rectal Indomethacin in the Prevention of post Endoscopic Retrograde Cholangio

Pancreatography (ERCP) Pancreatitis

Public title
Rectal Indomethacin and Sublingual Nitrates in prevention of post ERCP pancreatitis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
aged 18-70 Need for ERCP
Exclusion criteria:
Contraindications of nitroglycerin Contraindications of Indomethacin Pregnancy Lactation
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **324**
Actual sample size reached: **324**
Randomization (investigator's opinion)
Randomized
Randomization description
block randomization at the level of the individual
Blinding (investigator's opinion)
Double blinded
Blinding description
participants and the therapist does not know the allocation of people, and only the person who supplies the medication to the patients is aware of the type of allocation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qom University of Medical Sciences
Street address
No. 83, 4th alley, 1.1 alley, Safashahr Blvd
City
Qom
Province
Ghoum
Postal code
3716987366
Approval date
2016-06-23, 1395/04/03
Ethics committee reference number
IR.MUQ.REC.1395.43

Health conditions studied

1

Description of health condition studied
ERCP-induced pancreatitis
ICD-10 code
K85.8
ICD-10 code description
Other acute pancreatitis

Primary outcomes

1

Description
Pancreatitis
Timepoint
24 hours after ERCP
Method of measurement
Serum levels of pancreatic enzymes

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Indomethacin suppository, 100 mg, single dose, before ERCP plus nitroglycerin tablet, 0.4 mg, single sublingual, immediately after ERCP
Category
Treatment - Drugs

2

Description
Control group: Indomethacin suppository, 100 mg, single dose, before ERCP plus placebo tablet, single dose, sublingual, immediately after ERCP
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hosbital
Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
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Ghoum 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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Ahmad Hormati
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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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
The data are specific to this study
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available