

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of indomethacin suppository plus mesna injection versus indomethacin suppository in prevention of post Endoscopic Retrograde Cholangio-pnacreatography pancreatitis

Protocol summary

Study aim

Comparing the effect of single dose of rectal Indomethacin plus mesna injection versus single dose of rectal indomethacin on prevention of post Endoscopic Retrograde cho;angio-pancreatography pancreatitis

Design

A randomized, controlled clinical trial with a parallel group on 200 patients.

Settings and conduct

This trial will be done in Endoscopy ward of Talighani hospital, Tehran. 200 patients with indication of Endoscopic Retrograde Cholangiopancreatography will be considered for the study. All patients will receive 100 mg indomethacin rectally just before doing procedure. Patients divided in two groups; to receive the mesna or nothing. Patients in the mesna group received two 400 mg injection of mesna before doing Cholangiopancreatography. All patients were followed-up for occurrence of post Endoscopic Retrograde Cholangiopancreatography pancreatitis. Endoscopic Retrograde Cholangiopancreatography pancreatitis will be defined as severe abdominal pain that necessitate hospitalization of a minimum of 48 hours and an elevated serum amylase/serum lipase level of more than 3 times the upper limit of normal. The rate of pancreatitis will be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 200 patients who undergo Endoscopic Retrograde Cholangiopancreatography between 20 to 80 years old and by taking consent form will be enrolled in this study. Exclusion criteria: patients with history of hypersensitivity to each of indomethacin or mesna.

Intervention groups

Group1: Administration of single dose of 100 mg rectal indomethacin just before plus mesna injection 400 mg before doing Endoscopic cholangiopancreatography
Group2: Administration of single dose of 100 mg rectal

indomethacin just before doing Endoscopic cholangiopancreatography

Main outcome variables

Pancreatitis occurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121021011192N16**

Registration date: **2023-10-13, 1402/07/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-13, 1402/07/21**

Update count: **0**

Registration date

2023-10-13, 1402/07/21

Registrant information

Name

Mohammad Abbasinazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

m_abbasi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-05, 1403/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of indomethacin suppository plus mesna injection versus indomethacin suppository in prevention of post Endoscopic Retrograde Cholangio-pncreatography pancreatitis

Public title
Comparing the rectal Indomethacin plus Mesna versus rectal indomethacin on prevention of post Endoscopic Retrograde Cholangio-pncreatography pancreatitis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing ERCP in Taleghani hospital by taking written consent
Exclusion criteria:
Patients history of hypersensitivity against each of indomethacin or mesna Patients history of sphinctrotomy

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **698**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

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
shahid beheshti university of medical sciences, Arabi

street, velenjak
City
Tehran
Province
Tehran
Postal code
26785434
Approval date
2023-10-01, 1402/07/09
Ethics committee reference number
IR.SBMU.RETECH.REC.1402.341

Health conditions studied

1

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

Primary outcomes

1

Description
Pancreatitis
Timepoint
10 days after doing Endoscopic Retrograde Cholangio-pancreatography
Method of measurement
Clinical evaluation

Secondary outcomes

1

Description
Gastrointestinal bleeding
Timepoint
10 days after doing Endoscopic Retrograde Cholangio-pancreatography
Method of measurement
Clinical evaluation

Intervention groups

1

Description
Intervention group: Administration of single dose of 100 mg rectal Indomethacine plus 400 mg infusion of mesna 1 hours before doing Endoscopic cholangiopancreatograph
Category
Prevention

2

Description

Control group: Administration of single dose of 100 mg rectal Indomethacine 1 hours before doing Endoscopic cholangiopancreatograph

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

School of pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Abbasinazari

Street address

School of Pharmacy, Nyayesh junction, Valiasr street

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1996835113

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m_abbasi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ardeshir Tajbakhsh

Street address

Anesthesia research center, Talighani hospital. Arabi street

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23435676

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ardeshir.tj@yahoo.com

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

Mohammad Abbasinazari

Position

full professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

All data can be shared after deidentified

When the data will become available and for how long

starting in July 2024

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

with written consent

From where data/document is obtainable

Sending email to: m_abbasi@sbmu.ac.ir

What processes are involved for a request to access data/document

Sending email to: m_abbasi@sbmu.ac.ir

Comments