Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of indomethacin suppository plus mesna injection verusus 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 recieve 100 mg indomethacin rectally just before doing procedure. Patients devided 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 defined 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 inform will be enrolled in this study. Exclusion criteria: patients with history of hypersensitivity to each of indomethacin or mesna.

Intervention groups
Group1: Adminstration of single dose of 100 mg rectal indomethacine 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 occurence

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)

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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 verusus indomethacin suppository in prevention of post Endoscopic Retrograde Cholangio-pnacreatography pancreatitis

Public title
Comparing the rectal Indomethacin plus Mesna versus rectal indomethacin on prevention of post Endoscopic Retrograde Cholangio-pnacreatography 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 Behesti University of Medical Sciences
Full name of responsible person
Mohammad Abbasinazari
Street address
School of Pharmacy, Nyayesh junction, Valiasr street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ardeshir Tajbakhsh
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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 updating data

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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