Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of rectal Indomethacin, Diclofenac or Naproxen on prevention of post Endoscopic cholangiopancreatography pancreatitis

Protocol summary

Summary

Aim: Evaluation and comparison of single dose of rectal Indomethacin, Diclofenac or Naproxen in prevention of post ERCP pancreatitis Inclusion Criteria: During 1 year, all patients who undergo ERCP by taking consent inform will be enrolled in this study. Exclusion criteria: patients who will undergo a prior endoscopic sphincterotomy. Studied Patients: In a double-blind controlled randomized trial, patients will receive a suppository containing 100 mg of indomethacin or diclofenac 100 mg or Naproxen 500 mg just before doing ERCP. Primary outcomes: Serum lipase and amylase levels will be measured in all patients after ERCP after 12 hours. Also clinical parameters will be evaluated including abdominal pain and number of admitted days in the ward and pancreatitis will be scored.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100111192N3**
Registration date: **2014-11-08, 1393/08/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-11-08, 1393/08/17

Registrant information

Name
Mohammad Abbasinazari
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source
Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2016-01-01, 1394/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of rectal Indomethacin, Diclofenac or Naproxen on prevention of post Endoscopic cholangiopancreatography pancreatitis

Public title

Effect of indomethacin,diclofenac or naproxen on prevention of pancreatitis

Purpose

Prevention

Inclusion/Exclusion criteria

Patients undergoing ERCP in Taleghani hospital by taking written consent

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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, Deputy of Reserch, School of Pharmacy, Shahid Beheshti University of Medical Scien
Street address
School of Pharmacy, Nyayesh junction, Valiasr street
City
Tehran
Postal code
Approval date
2014-09-02, 1393/06/11
Ethics committee reference number
23546

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 ERCP
Method of measurement
clinical evaluation

Secondary outcomes

1

Description
gastrointestinal bleeding
Timepoint
10 days after doing ERCP
Method of measurement
clinical evaluation

2

Description
Hypersensitivity reactions
Timepoint
10 days after doing ERCP
Method of measurement
Clinical observation

Intervention groups

1

Description
Group1: Adminstration of single dose of 100 mg rectal indomethacine just before doing Endoscopic cholangiopancreatography Group2: Administration of single dose of 100 mg rectal diclofenac just before doing Endoscopic cholangiopancreatography Group 3: Administration of single dose of 500 mg rectal naproxen just before doing Endoscopic cholangiopancreatography
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research, School of Pharmacy, Shahid Beheshti Universty of Medical Sciences
Full name of responsible person
Nima Naderi
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School of Pharmacy, Nyayesh junction, Valiasr street
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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
Deputy of Research, School of Pharmacy, Shahid Beheshti Universty of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty