

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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

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

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

Street address

School of Pharmacy, Nyayesh junction, Valiasr street

City

Tehran

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

Street address

School of Pharmacy, Nyayesh junction, Valiasr street

City

Tehran

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 University 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

Name of organization / entity
School of pharmacy, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Abbasinazari
Position
PhD in Clinical pharmacy
Other areas of specialty/work
Street address
School of Pharmacy Nyayesh junction, Valiasr street
City
Tehran
Postal code
Phone
+98 21 8887 3704
Fax
Email
m_abbasi@sbmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of pharmacy, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Abbasinazari

Position
PhD in Clinical Pharmacy
Other areas of specialty/work
Street address
School of Pharmacy, Nyayesh junction, Valiasr street
City
Tehran
Postal code
Phone
+98 21 8887 3704
Fax
Email
m_abbasi@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
School of Pharmacy Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Abbasinazari
Position
PhD in Clinical Pharmacy
Other areas of specialty/work
Street address
School of Pharmacy, Nyayesh junction, Valiasr street
City
Tehran
Postal code
Phone
+98 21 8887 3704
Fax
Email
Web page address

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