

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effect of Celecoxib in the prevention of pancreatitis after Endoscopic retrograde cholangiopancreatography (ERCP)

Protocol summary

Summary

Acute pancreatitis is the most common and most feared complication during Endoscopic retrograde cholangiopancreatography (ERCP) and it has high prevalence of mortality and morbidity rarely. one risk factor for this complication is cannulation in pancreatobiliary duct during ERCP. Observed that the use of medications such as nonsteroidal anti-inflammatory drugs may prevent this complication. This study is a placebo-controlled clinical trial with simple sampling. Persons between 15 to 55 years without advanced systemic disease and were not drug addicts or continuous drug use and with mild hepatobiliary disease without fibrosis or cirrhosis are enrolled. If patient has no desire to continue study or in other complications after ERCP are excluded. Two groups of 38 patients enrolled in the drug group that use Celecoxib capsule 3 capsule 100mg and the placebo group that use 3 capsule 100mg placebo capsule manufacturing pharmaceutical Sajad, 5 hours before the intervention. serum amylase level is measured at capsule use time and 2 hours after intervention and patient is evaluate about pancreatitis signs and symptoms until 2 hours after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207252417N8**
Registration date: **2012-08-06, 1391/05/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-06, 1391/05/16

Registrant information

Name

Firouzeh Moeinzadeh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1625 5555

Email address

moinzade@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-08-21, 1391/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Celecoxib in the prevention of pancreatitis after Endoscopic retrograde cholangiopancreatography (ERCP)

Public title

Effect of Celecoxib in the prevention of pancreatitis after Endoscopic retrograde cholangiopancreatography (ERCP)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1- no advanced systemic disease 2- no addiction 3- no continuous drug use 4- mild hepatobiliary disease with liver enzyme elevation to 4 times of normal upper limit. 5- without fibrosis, cirrhosis

or infectious hepatitis exclusion criteria: 1- other side effects except pancreatitis after ERCP 2- Lack of consent to cooperate in trial.

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research, Isfahan University of Medical Sciences

Street address

Hezar Jarib street

City

Isfahan

Postal code

Approval date

2011-11-09, 1390/08/18

Ethics committee reference number

390375

Health conditions studied

1

Description of health condition studied

Acute Pancreatitis

ICD-10 code

K85.8

ICD-10 code description

Other acute pancreatitis

Primary outcomes

1

Description

Pancreatitis

Timepoint

Before and 2 hours after Endoscopic retrograde cholangiopancreatography

Method of measurement

Pain and clinical signs

2

Description

Serum amylase level

Timepoint

Before and 2 hours after Endoscopic retrograde cholangiopancreatography

Method of measurement

ELISA kits: International Unit per Litre

Secondary outcomes

empty

Intervention groups

1

Description

Cap celecoxib 100mg, 3 capsules. Sajjad Pharmaceutical Company, Mashad. 5 hours before Endoscopic retrograde cholangiopancreatography

Category

Treatment - Drugs

2

Description

Cap Placebo, 3 capsules. Sajjad Pharmaceutical Company, Mashad. 5 hours before Endoscopic retrograde cholangiopancreatography

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital, Endoscopy Department

Full name of responsible person

Dr. Zhaleh Derakhshan

Street address

Alzahra Hospital

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Peyman Adibi

Street address

Hezar Jarib Street. Isfahan University of Medical Sciences

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Isfahan 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**

Isfahan University of Medical Science

Full name of responsible person

Dr zhaleh derakhshan

Position

Internal Medicine Resident

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Mohammad Minakari

Position

Associate Professor of Gastroenterology

Other areas of specialty/work**Street address**

Alzahra hospital, Gastroenterology ward.

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Person responsible for updating data

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Isfahan University of Medical Sciences

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Dr Firouzeh Moeinzadeh

Position

Internist

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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