

# 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**

Alzahra hospital

**City**

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mona.derakhshan@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Isfahan University of Medical Science

**Full name of responsible person**

Dr Mohammad Minakari

**Position**

Associate Professor of Gastroenterology

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Alzahra hospital, Gastroenterology ward.

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## Person responsible for updating data

**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Firouzeh Moeinzadeh

**Position**

Internist

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

Alzahra Hospital

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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*