

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Evaluation of the effect of sublingual isosorbide dinitrate + indomethacin suppository in prevention of post Endoscopic retrograde colangiopancreatography (ERCP) pancreatitis

#### Protocol summary

##### Summary

Aim of the study: Pancreatitis is the most common complication after Endoscopic retrograde colangiopancreatography (ERCP) procedure and usually ends to long hospitalization. In severe cases it ends to complications that needs to surgical intervention and sometimes it causes death. It seems that sublingual isosorbide is effective for prevention of post ERCP pancreatitis. In this study we want to assess the influence of sublingual isosorbide with indomethacin suppository in prevention of post ercp pancreatitis. Study population: study population, are pancreatobilliary patients that must undergo ercp so they are introduced to endoscopy ward of shariati hospital that includes a population of 300 people who have the inclusion criteria of this study. All people who refer to ERCP ward of Shariati hospital will be included in our study if they have inclusion criteria of our study. Understudy intervention and primary outcomes: if they have inclusion criteria of our study, number one form will be filled with a general physician. 5 minutes before ercp procedure the case group take one pill of sublingual isosorbide and the control group will take placebo. All the patients will take indomethacin 100 mg, 5 minutes before the procedure. Serum amylase is measured 2 and 24 hours after ercp and patients will be assessed for pancreatitis signs and drug side effects and data will be registered in number 2 form. After each 3 months until the end of the study patient codes will be opened and sectional analysis will be evaluated and final results will be presented at the end of the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138810082931N1**

Registration date: **2012-11-19, 1391/08/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-11-19, 1391/08/29

##### Registrant information

###### Name

Rasoul Sotoudehmanesh

###### Name of organization / entity

Digestive Disease Research Center

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8241 5225

###### Email address

setoodeh@ams.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Digestive Disease Research center

##### Expected recruitment start date

2011-02-20, 1389/12/01

##### Expected recruitment end date

2014-02-20, 1392/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of sublingual isosorbide dinitrate + indomethacin suppository in prevention of post

Endoscopic retrograde colangiopancreatography (ERCP) pancreatitis

### Public title

Assessment of the effect of sublingual isosorbide dinitrate with indomethacin suppository on post Endoscopic retrograde colangiopancreatography pancreatitis

### Purpose

Prevention

### Inclusion/Exclusion criteria

Inclusion criteria: Study populations are all patients referred to Shariati hospital who undergo therapeutic or diagnostic ERCP in endoscopy ward. Exclusion criteria: age<18; HX of nitrate use; HX of recent acute pancreatitis (less than one month); HX of chronic pancreatitis; recent (2weeks) peptic ulcer bleeding; HX of glaucoma; ampullary tumor; use of sildenafil; unwilling for consent; allergy to drugs; previous sphincterotomy.

### Age

From **18 years** old to **100 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **300**

### 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

Digestive Disese Research Center

##### Street address

Shariati hospital, North Kargar

##### City

Tehran

##### Postal code

#### Approval date

2011-08-20, 1390/05/29

#### Ethics committee reference number

416/548

## Health conditions studied

### 1

#### Description of health condition studied

pancreatitis

#### ICD-10 code

K85.0

#### ICD-10 code description

Idiopathic acute pancreatitis

## Primary outcomes

### 1

#### Description

post ercp pancreatitis

#### Timepoint

24 hours after ercp

#### Method of measurement

pain observational scale, serum amylase measurement, hospitalation period

## Secondary outcomes

### 1

#### Description

nausea and vomiting

#### Timepoint

24 hours after procedure

#### Method of measurement

asking from patient

### 2

#### Description

fever/chills

#### Timepoint

2 and 24 hours after procedure

#### Method of measurement

check of fever grade with thermometer

### 3

#### Description

upper GI bleeding

#### Timepoint

2 and 24 hours after procedure

#### Method of measurement

check of vital signs, hematemesis and melena

## Intervention groups

### 1

#### Description

indomethacin 100 mg anal with sublingual tablet of isosorbide dinitrate 5 mg

#### Category

Treatment - Drugs

## 2

### Description

indomethacin 100 mg anal with sublingual placebo of isosorbide dinitrate 5 mg

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Digestive Disease Research Center

##### Full name of responsible person

##### Street address

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Digestive disease research center

##### Full name of responsible person

Rasoul Sotoudehmanesh

##### Street address

Shariati hospital, At the end of kargar street, postal code 14117-13135

##### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Digestive disease research center

#### 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

Digestive Disease Research Center

##### Full name of responsible person

Maryam Farsinejad

##### Position

Research Fellow.MD

#### Other areas of specialty/work

#### Street address

Digestive Disease Research Center, Shariati Hospital

#### City

Tehran

#### Postal code

#### Phone

+98 21 8241 5770

#### Fax

#### Email

maryfnm@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Digestive Disease Research Center

##### Full name of responsible person

Rasoul Sotoudehmanesh

##### Position

fellowship of gastroenterology

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##### Street address

Shariati Hospital, North kargar

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setoodeh@ams.ac.ir , r.sotoudehmanesh@gmail.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

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Maryam Farsinejad

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14114

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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*