

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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: Panceatitis 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 observative 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 sighns, 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

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Position

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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