Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 pancratitis
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 termometer

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
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Maryam Farsinejad
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www.ddri.ir

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