

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of three methods of Naproxen ,Isosorbide Dinitrate and concurrent use of them in prevention of Post- ERCP Pancreatitis

Protocol summary

Summary

Objectives: This study was scheduled with the aim of the effect of three methods of Rectal Naproxen Suppository, Isosorbide Dinitrate tablets and concurrent use of Rectal Naproxen Suppository with Isosorbide Dinitrate tablets in the prevention of Post-ERCP (Endoscopic Retrograde Cholangiopancreatogram) Pancreatitis in patients referred to Razi Hospital. Design: In this double-blind clinical trial (phase 3) with a sample size of 585, patients are randomized into three intervention groups. Also, they are examined in order to pancreatitis. Setting and conduct: due to sedation before ERCP, Lidocaine oral spray and Midazolam injection 0.05 mg/kg are applied. If Midazolam is contraindicated, Pethidine injection 1 mg/kg will be used. Therefore, the intervention will be performed. At the end of the ERCP the followings are registered: age, gender, and the details of procedure including: the total required time for the bile duct cannulation, final diagnosis, Implementations of sphincterotomy, injected contrast agent into the pancreatic duct and the presence or absence of Juxtapapillary diverticulum are stated. All the patients are considered in terms of acute pancreatitis up to 24 hours. Exclusion criteria: Acute pancreatitis in the last 2 weeks and history of chronic pancreatitis. Intervention: Intervention group 1: The group that received 500 milligram Rectal Naproxen Suppository once immediately before ERCP (Manufacturing factory is Behvazan); Intervention group 2: Isosorbide Dinitrate tablets 5 milligram once immediately before ERCP (Manufacturing factory is UCB Pharma GmbH); Intervention group 3: Concurrent use of naproxen suppository 500 milligram and Isosorbide Dinitrate tablets 5 milligram once immediately before ERCP. Main outcome measures: serum levels of amylase 2 and 24 hours after ERCP.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409251155N22**

Registration date: **2015-10-14, 1394/07/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-14, 1394/07/22

Registrant information

Name

Farahnaz Joukar

Name of organization / entity

Guilan University of Medical Sciences,
Gastrointestinal and liver disease Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 1553 5116

Email address

info@glrc.org

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Guilan University of
Medical Sciences

Expected recruitment start date

2015-06-07, 1394/03/17

Expected recruitment end date

2016-02-22, 1394/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of three methods of Naproxen ,Isosorbide Dinitrate and concurrent use of them in prevention of Post- ERCP Pancreatitis

Public title

Comparison of effect of three methods of Rectal Naproxen Suppository, Isosorbide Dinitrate tablets and concurrent use of Rectal Naproxen Suppository with Isosorbide Dinitrate tablets in Prevention of Post-Endoscopic Retrograde Cholangio Pancreatography (ERCP) pancreatitis in patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All patients over 18 years who were referred to Razi Hospital of Rasht for ERCP. Exclusion criteria: Acute pancreatitis in the last two weeks; history of chronic pancreatitis; a history of previous sphincterotomy; NSAID or Nitrate usage in a week prior and contraindication for NSAID or Nitrate usage like renal failure; recent Peptic Ulcer disease with recent GI Bleeding; Hypotension and Hypersensitivity to recent Each of the two drugs and lack of satisfaction of participate in this study.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **585**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gastrointestinal and Liver Disease Research Center of Guilan University of Medic

Street address

Namjoo Street

City

Rasht

Postal code

Approval date

2014-07-14, 1393/04/23

Ethics committee reference number

1930175708

Health conditions studied

1

Description of health condition studied

Post ERCP Pancreatitis

ICD-10 code

k85.8

ICD-10 code description

Other Acute Pancreatitis

Primary outcomes

1

Description

serum levels of Amylase

Timepoint

Two hours after ERCP

Method of measurement

Laboratory Kit

2

Description

symptoms of nausea, vomiting and abdominal pain

Timepoint

2 hours after ERCP

Method of measurement

Observations with check list

Secondary outcomes

1

Description

serum levels of Amylase

Timepoint

24 hours after ERCP

Method of measurement

Laboratory Kit

2

Description

symptoms of nausea, vomiting and abdominal pain

Timepoint

24 hours after ERCP

Method of measurement

Observation with check list

Intervention groups

1

Description

Intervention group 1: Rectal Naproxen Suppository, 500 milligram, once immediately before ERCP, Manufacturing factory is Behvazan

Category

Prevention

2

Description

Intervention group 2: Isosorbide Dinitrate tablets, 5 milligram, once immediately before ERCP, Manufacturing factory is UCB Pharma GmbH

Category

Treatment - Drugs

3

Description

Intervention group 3: Concurrent use of naproxen suppository 500 milligram and Isosorbide Dinitrate tablets 5 milligram once immediately before ERCP

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal Clinic of Razi Hospital

Full name of responsible person

Farahnaz Joukar

Street address

Gastrointestinal and Liver Diseases Research Center, Razi Hospital, Sardare Jangal Avenue, Guilan province, IRAN

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Dr. Rasool Tabari KHomeirani

Street address

Sadati st, Namjoo st, Rasht, Guilan

City

Rasht

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 of Guilan University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Behvazan Company

Full name of responsible person

Dr. seyed Mohamad Keshavarz

Street address

Behvazan Company, Rasht industrial city

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Behvazan Company

Proportion provided by this source

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

Gastrointestinal and Liver Disease Research Center (GLDRC)

Full name of responsible person

Farahnaz Joukar

Position

Assistant of Gastrointestinal and Liver Disease Research Center (GLDRC)

Other areas of specialty/work

Street address

Gastrointestinal and Liver Disease Research Center (GLDRC), Razi Hospital, Sardar Jangal Ave, Guilan province, IRAN

City

Rasht

Postal code

41448-95655

Phone

+98 13 3353 5116

Fax

Email

F_Jokar@gums.ac.ir

Web page address

www.gldrc.org

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gastrointestinal and Liver Disease Research Center (GLDRC)

Full name of responsible person

Dr.Fariborz Mansour-Ghanaei

Position

Professor of Gastroenterology and Hematology
Guilan, Chief of Gastrointestinal and Liver Disease Res

Other areas of specialty/work

Street address

Gastrointestinal and Liver Disease Research Center (GLDRC), Razi Hospital, Sardar Jangal Ave, Guilan province, IRAN

City

Rasht

Postal code

Phone

+98 13 1553 5116

Fax

Email

ghanaei@gums.ac.ir

Web page address

www.gldrc.org

Person responsible for updating data

Contact

Name of organization / entity

Gastrointestinal and Liver Disease Research Center

Full name of responsible person

Sara Mavaddati

Position

Bachelor of Cellular & Molecular Biology

Other areas of specialty/work

Street address

Gastrointestinal and Liver Disease Research Center (GLDRC), Razi Hospital, Sardar Jangal Ave, Guilan province, IRAN

City

Rasht

Postal code

Phone

00

Fax

Email

mavaddati.sara@gmail.com

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