

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of suppository naproxen in prevention of post ERCP pancreatitis in patients referred to RAZI hospital in RASHT

Protocol summary

Summary

Efficacy of suppository naproxen in prevention of post ERCP pancreatitis in patients referred to RAZI hospital in RASHT, the study population is all patients who were referred for ERCP to Razi hospital. Inclusion criteria: All patients over 18 years who were referred to hospital for ERCP or disorders in liver function tests or had extrahepatic cholestasis. Exclusion criteria: Acute pancreatitis in the last two weeks or history of chronic pancreatitis and a history of previous sphincterotomy and NSAID use in a week and contraindication for NSAID use, peptic ulcer with recent GI bleeding and not consent to participate in this plan. During the study people with inclusion criteria assign randomly to two groups. Case group take suppository naproxen (500 miligram) just before surgery and control group take placebo. The main consequence of study is pancreatitis. All patients are monitored of pancreatitis till 24 hours. Patients with abdominal pain and scores more than 3 times the enzyme amylase in 24 hours after surgery are considered pancreatitis. Serum amylase is checked 2 hours after ERCP, if there is no clinical pancreatitis, the patient will start to eat normally but if it be more than 3 times of normal and the patient have abdominal pain, nausea and vomiting, he/she will be NPO and prescribed intravenous fluids and narcotic for its pain. After 24 hours, amylase will be checked, patient be examined again and pancreatitis is confirmed with back and epigastric pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105301155N14**

Registration date: **2013-02-10, 1391/11/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-02-10, 1391/11/22

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@gldrc.org

Recruitment status

Recruitment complete

Funding source

Vince chancellor for reaserch Guilan University of Medical Sciences

Expected recruitment start date

2013-02-15, 1391/11/27

Expected recruitment end date

2014-09-15, 1393/06/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of suppository naproxen in prevention of post ERCP pancreatitis in patients referred to RAZI hospital in RASHT

Public title

Efficacy of suppository naproxen in prevention of

pancreatitis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: All patients over 18 years who were referred to hospital for ERCP; disorders in liver function tests; had extrahepatic cholestasis. Exclusion criteria: Acute pancreatitis in the last two weeks; history of chronic pancreatitis; a history of previous sphincterotomy; NSAID use in a week; contraindication for NSAID use such as renal failure and having allergy to the drug; peptic ulcer with recent GI bleeding; not consent to participate in this plan.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **324**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Guilan University of Medical Sciences. Ethics Committee Gastrointestinal and Liver Diseases Research

Street address
Sardar jangle Ave-Razi hospital-Gastrointestinal and liver disease research center.

City
Rasht

Postal code
41448-95655

Approval date
2011-05-26, 1390/03/05

Ethics committee reference number
160/1/ش

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
24 hours after ERCP

Method of measurement
Amylase serum, Patient's symptoms(nausea, vomiting and abdominal pain)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group take naproxen supp. 500 miligram just before ERCP.

Category
Prevention

2

Description
Control group take placebo suppository.

Category
Placebo

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 Hospita, Sardare Jangal Avenue

City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behvazan Company

Full name of responsible person

Dr. Seyed Mohamad Keshavarz

Street address

Rasht industrialcity Behvazan Company

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

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

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.

City

Rasht

Postal code

Phone

+98 13 1553 5116

Fax

Email

F_jokar@gums.ac.ir

Web page address

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

Head / Full Professor of Internal Medicine & Gastroenterology

Other areas of specialty/work

Street address

Gastrointestinal and Liver Disease Research Center (GLDRC) , Razi hospital , Sardar Jangal Ave.

City

Rasht

Postal code

Phone

+98 13 1553 5116

Fax

Email

ghanaei@gums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Gastrointestinal and liver disease research center

Full name of responsible person

Dr. Maryam Bakhshandeh

Position

Researcher/General Physician

Other areas of specialty/work

Street address

Gastrointestinal and Liver Disease Research Center (GLDRC) , Razi hospital , Sardar Jangal Ave.

City

Rasht

Postal code

Phone

+98 13 1553 5116

Fax

Email

bmaryamb@yahoo.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