

# 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.

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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.

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#### **Postal code**

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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*