

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Effect of pancreatic duct stenting before common bile duct (CBD) cannulation for preventing post endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis in patients attending in Firoozgar hospital

Protocol summary

Summary

Pancreatitis is one of the main complications of ERCP by the 5-15% incidence. It seems that the inducing factor is problem in pancreatitis due to drainage. The aim of this study is the comparison incidence of post-ERCP pancreatitis among intervention and control groups. This is a single blind balanced controlled-trial that will be done in Firoozgar hospital by 96 samples. The patients who had the pancreatitis before ERCP will be excluded and all of patients who are eligible for ERCP implementation will be included in study. The primary outcome is the incidence of pancreatitis in both groups of study. The allocations of intervention and control groups are non-random and patients will be blind from type of intervention. The baseline characteristics are age, sex and serum amylase. The descriptive analysis, Chi-Square tests and logistic regression will be used for data analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201018575N1**

Registration date: **2013-06-24, 1392/04/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-24, 1392/04/03

Registrant information

Name

Hossein Ajdarkosh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

The required tests are done in the hospital. The tests are needed in each case even without stent. The using stents are Endoflex made in German; that the cost of it would be asked from the annually income of research center.

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pancreatic duct stenting before common bile duct (CBD) cannulation for preventing post endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis in patients attending in Firoozgar hospital

Public title

Effect of stent in pancreatic duct for preventing pancreatitis complications

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria are: 1- Difficult cannulation that takes more than 15 minutes time; 2- Precut in Vater ampulla while endoscopic retrograde cholangiopancreatography (ERCP); 3- Oddi sphincter dysfunction; 4- Three times duct catheterization with guide; 5- One time duct catheterization with catheter; 6- Duct contrast injection for patients who had at least one above criteria. The main exclusion criteria are patients who have pancreatitis before intervention. In this situation, the diagnosis of induced pancreatitis from ERCP is difficult.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 96

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

We will study two groups that the ERCP will be done for both of them but only for one group (as Intervention group) put stent. Both of putting and no putting of stent have been approved theoretically and practically. The main goal of this study is the comparison incidence of post-ERCP pancreatitis among intervention and control groups.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

Street address

The central headquarters building, Iran University of Medical Sciences, The corner of Milad hospital, Hemmat highway, Tehran

City

Tehran

Postal code**Approval date**

2012-04-20, 1391/02/01

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Common Bile Duct (CBD) stone

ICD-10 code

K80.5

ICD-10 code description

Calculus of bile duct without cholangitis or cholecystitis

Primary outcomes**1****Description**

Pancreatitis

Timepoint

Patient's Amylase: 1- before ERCP. 2- during 6 and 18 hours after ERCP / after ERCP symptoms in patients are examined and investigated by a physician.

Method of measurement

According to serum amylase measurement and symptoms such as abdominal pain

2**Description**

Putting stents in the pancreatitis duct

Timepoint

While bile duct cannulation in patients having inclusion criteria

Method of measurement

Intraoperative observation

Secondary outcomes**1****Description**

Serum amylase

Timepoint

Before ERCP, within 6 and 18 hours post ERCP

Method of measurement

The patients' blood sampling (Mg/ dl)

Intervention groups**1****Description**

In the intervention group, according to the accidental cannulation of pancreatic duct, a plastic stent 5cm and 5f (French) is placed in the pancreatic duct, and then ERCP will be done. In the control group, standard ERCP will be done (without putting stent). Stent will be done.

Category

Prevention

2

Description

In the control group, standard ERCP without stenting is done, and the results would be compared with the case group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Hossein Ajdarkosh

Street address

Firoozgar hospital, Behafarin St., Valiasr Sq., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Seyyed- Abbas Motevallian

Street address

The central headquarters building, Iran University of Medical Sciences, The corner of Milad hospital, Hemmat highway, Tehran

City

Tehran

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, Iran University of Medical Sciences

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

Firoozgar Hospital

Full name of responsible person

Hossein Ajdarkosh

Position

Gastroenterologist

Other areas of specialty/work

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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