

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Prophylactic effect of rectal indomethacin administration, with and without intravenous hydration, on the development of pancreatitis after retrograde cholangiopancreatography

Protocol summary

Summary

Overall, 406 patients who have fulfilled the criteria for undergoing endoscopic retrograde cholangiopancreatography (ERCP) and who have fulfilled the inclusion and exclusion criteria have been enrolled in this randomized single blind clinical trial. The patients have been allocated into an intervention and a placebo group. Initially, every patient is given a number from 1 to 4 by an internist and then referred to a gastroenterologist at Ghaem Hospital to undergo ERCP. Those with numbers 1, 2 and 3 are given 100 mg indomethacin per rectum, intravenous normal saline, and both indomethacin and normal saline, respectively, two hours prior to the endoscopic procedure. Patients with the number 4 are consider as the control group and receive glycerin per rectum. Blood samples are taken from patients with abdominal pain and vomiting 2, 12 and 24 hours post-ERCP for hyper-amylasemia. The diagnosis of post-endoscopic pancreatitis (PEP) is confirm with serum amylase levels 3 times the upper limit of normal. Subsequently, the prevalence of pancreatitis will be evaluated in every group based on clinical and laboratory findings. Finally, the results will be recorded and analyzed using statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014082418915N1**

Registration date: **2014-10-24, 1393/08/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-24, 1393/08/02

Registrant information

Name

Mousalreza Hosseini

Name of organization / entity

Mashhad University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University Of Medical Sciences

Expected recruitment start date

2013-05-12, 1392/02/22

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic effect of rectal indomethacin administration, with and without intravenous hydration, on the development of pancreatitis after retrograde cholangiopancreatography

Public title

Effect of rectal indomethacin and intravenous hydration in the prevention of pancreatitis after endoscopic retrograde cholangiopancreatography (single blind clinical trial)

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Age>18y; Patients are eligible if they are diagnosed with choledocolithiasis. Exclusion criteria: Patients with previous unsuccessful sphincterotomy; Decreased state of consciousness; Cardiovascular, renal diseases and under dialysis patients; Increased risk of bleeding; Evident acute pancreatitis, chronic pancreatitis or pancreatic cancer; Hyperamylasemia (≥ 150 IU/L); Allergy or hypersensitivity to indomethacin or water-soluble contrast solutions; Having ingested NSAIDs a week earlier are enrol

Age
From **16 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **406**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashad University Of Medical Sciences
Street address
Goreyshi Building, Daneshgah Street, Mashad
University Of Medical Sciences
City
Mashhad
Postal code
00985138412081
Approval date
2013-05-11, 1392/02/21
Ethics committee reference number
911008

Health conditions studied

1

Description of health condition studied
Calculus of bile duct without cholangitis or cholecystitis
ICD-10 code
K80.5
ICD-10 code description
Choledocholithiasis

Primary outcomes

1

Description
Frequency of post endoscopic retrograde cholangiopancreatography pancreatitis
Timepoint
2,12,24 hours post endoscopic retrograde cholangiopancreatography.
Method of measurement
Clinical exam and serum amylase measurement

Secondary outcomes

empty

Intervention groups

1

Description
Placebo: Patients in the control group only receive rectal glycerin.
Category
Treatment - Drugs

2

Description
Intervention: Patients divide up into three study groups and receive the intervention 2 hours prior to the procedure. The patients in the first group receive 100 mg of rectal indomethacin.
Category
Treatment - Drugs

3

Description
The patients in the second group receive intravenous normal saline perfusion.
Category
Treatment - Drugs

4

Description
The patients in the third group receive both interventions.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mousalreza Hosseini

Street address

Internal Department, Ghaem Hospital, Ahmadabad Street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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Ghoreishi Building, Danseshgah Street, Research Vice Chancellery, Mashhad University of Medical Sciences

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashad 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**

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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