

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 80 1274 2513

###### Email address

hoseinimr@mums.ac.ir

##### 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 ( $\geq 150$  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

**Street address**

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

**City**

Mashhad

**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**

Mashad University Of Medical Sciences

**Full name of responsible person**

Mousalreza Hosseini

**Position**

Assistant Professor

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*