

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of Rectal Indomethacin and Nitroglycerin in Comparison with Rectal Indomethacin in the Prevention of post Endoscopic Retrograde Cholangio Pancreatography (ERCP) Pancreatitis

#### Protocol summary

##### Study aim

Impact of coadministration of rectal Indomethacin and Sublingual Nitrates in prevention of post ERCP pancreatitis

##### Design

In this research, 324 eligible patients needed ERCP referring to Qom gastroenterology clinic were chosen purposefully. Then, patients by block randomization were randomly divided into two control and intervention groups.

##### Settings and conduct

The study was performed as a randomized clinical trial at Shahid Beheshti Hospital in Qom. The study is double-blinded, and intervention is conducted by someone other than the care provider, and care provider and participants is unaware of the type of treatment.

##### Participants/Inclusion and exclusion criteria

People entering the study aged 18 to 70 years and patients who have contraindication for taking Indomethacin or Nitroglycerin were not included in the study.

##### Intervention groups

Intervention group: Indomethacin suppository, 100 mg, single dose, before ERCP plus nitroglycerin tablet, 0.4 mg, single sublingual, immediately after ERCP. Control group: Indomethacin suppository, 100 mg, single dose, before ERCP plus placebo tablet, single dose, sublingual, immediately after ERCP

##### Main outcome variables

Post ERCP pancreatitis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161205031252N5**

Registration date: **2018-01-18, 1396/10/28**

Registration timing: **retrospective**

Last update: **2018-01-18, 1396/10/28**

Update count: **0**

##### Registration date

2018-01-18, 1396/10/28

##### Registrant information

###### Name

Ahmad Hormati

###### Name of organization / entity

Qom university of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3612 2053

###### Email address

hormatia@muq.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-06-25, 1395/04/05

##### Expected recruitment end date

2016-09-22, 1395/07/01

##### Actual recruitment start date

2016-06-25, 1395/04/05

##### Actual recruitment end date

2016-09-22, 1395/07/01

##### Trial completion date

empty

##### Scientific title

Effect of Rectal Indomethacin and Nitroglycerin in Comparison with Rectal Indomethacin in the Prevention of post Endoscopic Retrograde Cholangio

Pancreatography (ERCP) Pancreatitis

## Public title

Rectal Indomethacin and Sublingual Nitrates in prevention of post ERCP pancreatitis

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

aged 18-70 Need for ERCP

### Exclusion criteria:

Contraindications of nitroglycerin Contraindications of Indomethacin Pregnancy Lactation

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **324**

Actual sample size reached: **324**

## Randomization (investigator's opinion)

Randomized

## Randomization description

block randomization at the level of the individual

## Blinding (investigator's opinion)

Double blinded

## Blinding description

participants and the therapist does not know the allocation of people, and only the person who supplies the medication to the patients is aware of the type of allocation.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

##### Street address

No. 83, 4th alley, 1.1 alley, Safashahr Blvd

##### City

Qom

##### Province

Ghorm

## Postal code

3716987366

## Approval date

2016-06-23, 1395/04/03

## Ethics committee reference number

IR.MUQ.REC.1395.43

## Health conditions studied

### 1

#### Description of health condition studied

ERCP-induced 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

Serum levels of pancreatic enzymes

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Indomethacin suppository, 100 mg, single dose, before ERCP plus nitroglycerin tablet, 0.4 mg, single sublingual, immediately after ERCP

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Indomethacin suppository, 100 mg, single dose, before ERCP plus placebo tablet, single dose, sublingual, immediately after ERCP

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hosbital

##### Full name of responsible person

Ahmad Hormati  
**Street address**  
Shahid Beheshti Hospital, Shahid Beheshti Blvd,  
Azadegan Square.  
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hormatia@muq.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ghoum University of Medical Sciences  
**Full name of responsible person**  
Hosein Saghafi  
**Street address**  
Namber 83, Alley 4, Alley 1.1, Safashahr Street  
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**Email**  
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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**  
Ghoum University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Ghoum University of Medical Sciences  
**Full name of responsible person**  
Ahmad Hormati

**Position**  
Assistant Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
Gastroenterology and Hepatology Disease Research  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Ghoum University of Medical Sciences  
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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The data are specific to this study

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available