

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of ERCP complications with Diclofenac suppository and Acetaminophen suppository patients with CBD stone

#### Protocol summary

##### Summary

Objectives: Determine the effects of ERCP complications in patients receiving Diclofenac suppository with patients receiving acetaminophen suppositories in patients with gallstones Design: Randomized, Not-blind. The main inclusion criteria to study: the need for ERCP (Endoscopic Retrograde Cholangiopancreatography) due to gallstones. The main exclusion criteria from study: presence of coagulation disorders have already been diagnosed; Taking medications that may interfere with coagulation tests. Intervention group: Diclofenac Suppository, Before ERCP Control group: Acetaminophen Suppositories, Before ERCP Primary outcome measure: Bleeding rate, During ERCP and during 24 hours after ERCP, By monitoring vital signs and clinical examination

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014020616504N1**

Registration date: **2014-03-02, 1392/12/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-03-02, 1392/12/11

##### Registrant information

##### Name

Hadi Bagheri Hosseini

##### Name of organization / entity

Imam Reza Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 915 840 3741

##### Email address

hadibagherihh1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

##### Expected recruitment start date

2014-01-11, 1392/10/21

##### Expected recruitment end date

2014-10-13, 1393/07/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of ERCP complications with Diclofenac suppository and Acetaminophen suppository patients with CBD stone

##### Public title

Determine the effects of ERCP complications in patients receiving diclofenac suppository with patients receiving acetaminophen suppositories in patients with gallstones

##### Purpose

Diagnostic

##### Inclusion/Exclusion criteria

The main inclusion criteria to study: the need for ERCP (Endoscopic Retrograde Cholangiopancreatography) due to gallstones. The main exclusion criteria from study: presence of coagulation disorders have already been diagnosed; Taking medications that may interfere with coagulation tests.

##### Age

No age limit

##### Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 140

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Vice Chancellor for Research of Mashhad University of Medical Sciences, Ghoreishi Building, Daneshgah Street, Mashhad

##### City

Mashhad

##### Postal code

##### Approval date

2014-01-11, 1392/10/21

##### Ethics committee reference number

911196

## Health conditions studied

### 1

#### Description of health condition studied

Nonsteroidal anti-inflammatory drugs

#### ICD-10 code

Y45.3

#### ICD-10 code description

Other nonsteroidal anti-inflammatory drugs

## Primary outcomes

### 1

#### Description

Bleeding rate

#### Timepoint

During ERCP and during 24 hours after ERCP

#### Method of measurement

Monitoring vital signs and clinical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Diclofenac Suppository, Once before ERCP

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Acetaminophen Suppositories, Once before ERCP

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Hadi Bagheri Hosseini

##### Street address

Imam Reza Hospital, Imam Reza Square, Mashhad

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research of Mashhad University of Medical Sciences

##### Full name of responsible person

Mohammad Ramezani

##### Street address

Vice Chancellor for Research of Mashhad University of Medical Sciences, Ghoreishi Building, Daneshgah Street, Mashhad

##### City

Mashhad

#### 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 of Mashhad 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**

Imam Reza Hospital

**Full name of responsible person**

Hadi Bagheri Hosseini

**Position**

Student of Subspecialist

**Other areas of specialty/work**

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**Full name of responsible person**

Abbas Esmaeelzadeh

**Position**

Subspecialist of Gastroenterology

**Other areas of specialty/work**

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Imam Reza Hospital

**Full name of responsible person**

Hadi Bagheri Hosseini

**Position**

Student of Subspecialist

**Other areas of specialty/work**

**Street address**

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**Phone**

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**Fax**

**Email**

Hadibagheri-h@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*