

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### The effect of magnesium sulfate on prevention of pancreatitis after ERCP (Endoscopic retrograde cholangiopancreatography)

#### Protocol summary

##### Study aim

The effect of magnesium sulfate on the prevention of pancreatitis after endoscopic rollback

##### Design

In this research, 270 patients with an indication of ERCP referring to Imam Khomeini Hospital will be selected randomly using random numbers table.

##### Settings and conduct

After performing ERCP, intervention group will receive IV magnesium sulfate and control group will receive IV placebo (normal saline). Patients will be examined after ERCP, and if they have pain according to pancreatitis, an amylase and lipase test will be performed for them. The study is double blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years  
Exclusion criteria: Renal failure; Heart block; Myasthenia gravis; Bradycardia; Pregnancy and lactation; Cirrhosis; Kidney stones; Sensitivity to magnesium..

##### Intervention groups

Intervention group: 2 g IV magnesium sulfate one hour before ERCP and 2 grams six hours after ERCP. Control group: 2 g of IV placebo (normal saline) one hour before ERCP and 2 g six hours

##### Main outcome variables

Incidence of pancreatitis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180310039017N1**  
Registration date: **2018-04-01, 1397/01/12**  
Registration timing: **prospective**

Last update: **2018-04-01, 1397/01/12**

Update count: **0**

##### Registration date

2018-04-01, 1397/01/12

##### Registrant information

###### Name

hoda hamid

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3441 1585

###### Email address

h-hamid@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-20, 1397/01/31

##### Expected recruitment end date

2018-08-22, 1397/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of magnesium sulfate on prevention of pancreatitis after ERCP (Endoscopic retrograde cholangiopancreatography)

##### Public title

Effect of magnesium sulfate in prevention of pancreatitis

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Age over 18 years

###### Exclusion criteria:

Renal failure GFR <60 Heart block Myasthenia gravis or other Neuromuscular diseases Pregnancy and lactation Bradycardia Cirrhosis kidney stones (calcium, magnesium, ammonium, phosphate)

#### Age

From **18 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Participant
- Investigator

#### Sample size

Target sample size: **270**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple randomization, using random numbers table that will be done individually.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Blinding will be done by encoding the pharmaceutical packs.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Central building of Tehran University of Medical Sciences, Qods street, Keshavarz Boulevard.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2017-12-18, 1396/09/27

#### Ethics committee reference number

IR.TUMS.IKHC.REC.1396.4292

## Health conditions studied

### 1

#### Description of health condition studied

Pancreatitis

#### ICD-10 code

K85

#### ICD-10 code description

Acute pancreatitis

## Primary outcomes

### 1

#### Description

Incidence of pancreatitis

#### Timepoint

After ERCP

#### Method of measurement

Examination by a physician and performing tests.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 2 g IV magnesium sulfate one hour before ERCP and 2 grams six hours after ERCP.

#### Category

Prevention

### 2

#### Description

Control group: 2 g of IV placebo (normal saline) one hour before ERCP and 2 g six hours after ERCP.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital Complex

##### Full name of responsible person

Dr. Hoda Hamid

##### Street address

Imam Khomeini Hospital Complex, The end of Keshavarz boulevard, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

##### Phone

+98 21 6691 1293

**Email**

h-hamid@razi.tums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Younesian

**Street address**

Central building of Tehran University of Medical Sciences, Qods Street, Keshavarz Boulevard.

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Tehran

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+98 21 6119 0000

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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**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Hoda Hamid

**Position**

Internist

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Imam Khomeini Hospital Complex, end of Keshavarz Boulevard

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**Province**

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

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**Phone**

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**Email**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

The main outcomes' data, including testing, interventions and results of intervention will be shared.

### When the data will become available and for how long

Access starts after the publication of the results.

### To whom data/document is available

Researchers of academic institutions

### Under which criteria data/document could be used

Presenting a Introduction letter from the University

### From where data/document is obtainable

E-mail: h-hamid@razi.tums.ac.ir Dr. Hoda Hamid

### What processes are involved for a request to access data/document

After receiving the request and the introduction letter, Tehran University of Medical Sciences will get permission and the file will be sent to them.

### Comments