

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Aug 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

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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
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Central building of Tehran University of Medical Sciences, Qods Street, Keshavarz Boulevard.
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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
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Person responsible for updating data

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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