

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the therapeutic effect of statin relative to the N-acetyl cysteine in the treatment of Helicobacter pylori patients

#### Protocol summary

##### Study aim

Evaluation of the frequency of Helicobacter negative and positive subjects after adjuvant treatment with statin we therefore decided to find out by designing this study whether it is possible to Should we use two drugs as adjunctive therapy to eradicate HP

##### Design

Patients are randomly divided into three groups, two intervention groups and one control group. Randomization will be done by block method with a block size of six. Double-blind randomization will be done by sealed envelopes.

##### Settings and conduct

In this clinical trial study, patients referred to the internal medicine and gastroenterology clinic of Qaim Hospital who were subjected to the stool HP antigen test due to dyspepsia to check for HP and reported a positive STEF test were included in the study if they were eligible and gave informed consent

##### Participants/Inclusion and exclusion criteria

Informed written consent Helicobacter pylori positive patients with definitive diagnosis by stool HP antigen test referring to Ghaem Hospital Age category 18 years and above

##### Intervention groups

Patients are randomly divided into three groups, two intervention groups and one control group The control group only received first-line treatment for HP eradication, which included amoxicillin at a dose of 1 g every 12 hours for 14 days, clarithromycin 500 mg every 12 hours for 14 days, and pantoprazole 40 mg daily for one month, and placebo They will be placed for 14 days. The first intervention group will receive rosavastatin 5 mg twice daily for 14 days in addition to the three-drug eradication therapy described above

##### Main outcome variables

The effectiveness of drugs in the treatment of Helicobacter pylori infection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231017059756N1**

Registration date: **2023-11-06, 1402/08/15**

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

Last update: **2023-11-06, 1402/08/15**

Update count: **0**

##### Registration date

2023-11-06, 1402/08/15

##### Registrant information

##### Name

Javad Aishy

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3822 6605

##### Email address

aishy.m5@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-23, 1402/08/01

##### Expected recruitment end date

2025-10-23, 1404/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the therapeutic effect of statin relative to the N-acetyl cysteine in the treatment of Helicobacter pylori patients

#### Public title

Investigating the therapeutic effect of statin relative to the N-acetyl cysteine in the treatment of Helicobacter pylori patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Informed written consent Helicobacter pylori positive patients with definitive diagnosis by stool HP antigen test referring to Ghaem Hospital Age category 18 years and above

##### Exclusion criteria:

Canceling the continuation of the plan pregnancy breastfeeding Weight loss of more than 5% over the past six months Dysphagia and positive personal or family history of gastrointestinal malignancy Receiving statin and NAC during the last 6 months Having a history of gastric surgery Receiving PPI and antibiotics in the past month The presence of known drug sensitivity to any of the drugs used Known liver problems The presence of obvious gastrointestinal bleeding Occurrence of possible drug side effects due to drug intervention and possible myopathy due to statin use

#### Age

From **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **180**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Using the site [www.randomization.com](http://www.randomization.com), in the randomization part of the site, after selecting create a list, specify the number of groups, block sizes and the length of the list, and based on that, randomization of the list is provided

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Sealed envelopes of medicine

#### Placebo

Used

#### Assignment

Crossover

#### Other design features

no

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mashhad University of Medical Sciences

##### Street address

Mashhad University of Medical Sciences

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9177137559

#### Approval date

2023-10-14, 1402/07/22

#### Ethics committee reference number

4020375

## Health conditions studied

### 1

#### Description of health condition studied

Helicobacter pylori patients

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Helicobacter pylori infection recovery rate

#### Timepoint

Before starting treatment and one month after starting treatment

#### Method of measurement

Based on Helicobacter pylori antigen test in stool exam

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: receiving a 14-day regimen of Helicobacter plus statin

#### Category

Other

### 2

#### Description

Intervention group: receiving a 14-day regimen of Helicobacter plus n a cystein

**Category**

Other

**3**

**Description**

Control group: Receiving a 14-day Helicobacter regimen with placebo

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Internal medicine and gastroenterology clinic of ghaem Hospital, Mashhad

**Full name of responsible person**

javad aishy

**Street address**

ahmad abad street ghaem hospital

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9177137559

**Phone**

+98 51 3822 6605

**Email**

aishy.m5@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Deputy of research and technology

**Street address**

Mashhad, Pirouzi Blvd., Delavaran St., Rahai St., Panch, Heydari Street, 1st floor, 29

**City**

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**Province**

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**Fax**

+98 51 3822 6605

**Email**

aishy.m5@gmail.com

**Web page address**

<https://www.mums.ac.ir/>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

javad aishy

**Position**

assistant of internal medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

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**Email**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

javad aishy

**Position**

assistant of internal medicine

**Latest degree**

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**Other areas of specialty/work**

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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

Yes - There is a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

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

All data is potentially shareable after de-identifying individuals

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

After the study was published

### To whom data/document is available

all people

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

all people

### From where data/document is obtainable

The site of the University of Medical Sciences and scientific sites Through direct communication with the researcher

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

There is no limit

### Comments

no

## Person responsible for updating data

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

javad aishy

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assistant of internal medicine

#### Latest degree

Medical doctor

#### Other areas of specialty/work

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