

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, 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

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Phone

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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

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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

Street address

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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

Position

assistant of internal medicine

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