

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Determining the efficacy of quadruple standard regimen combined with simvastatin, probiotic, and NAC as adjuvant therapy for H. Pylori eradication and comparing to standard treatment

Protocol summary

Study aim

Evaluation and therapeutic efficacy of Helicobacter pylori eradication protocol by adding each of the drugs simvastatin, probiotics and N-acetylcysteine (NAC)

Design

Individuals (162 patients) are divided into four groups of 42 in each group based on random permutations. Phase 2-3

Settings and conduct

Patients with positive helicobacter pylori infection in the gastroenterology clinic of Imam Hossein Hospital who meet the inclusion criteria. After collecting demographic, clinical and medical records or previous treatments, patients will be randomly assigned to one of four intervention groups: 1) four drugs (metronidazole, amoxicillin, pantoprazole and bismuth, 2) four drugs with probiotics yasimvastatin. or NAC for two weeks . Evaluation by stool antigen tests and Clinical signs one month after treatment

Participants/Inclusion and exclusion criteria

People over 18 years and under 65 years of age are non-pregnant and with positive stool or endoscopic antigen test for Helicobacter pylori without history of heart failure, kidney and liver failure, no diabetes, no active cancer, no drug and alcohol addiction, no history of receiving previous treatment and no recent history of gastrointestinal bleeding.

Intervention groups

After collecting baseline information including demographic characteristics, clinical manifestations, and previous medical or therapeutic records, patients were divided into four intervention groups: 1) The standard four-drug protocol receiving group (metronidazole 250 mg, amoxicillin 1000 mg, pantoprazole 40 mg and bismuth 120 mg) all twice a day, 2) the four-drug protocol receiving group with probiotics (250 mg daily), 3) four-drug protocol group with simvastatin (10 mg

daily) and 4) four-drug protocol group with NAC (600 mg daily).

Main outcome variables

Comparison of Helicobacter pylori eradication in the study groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220406054431N1**

Registration date: **2022-05-08, 1401/02/18**

Registration timing: **prospective**

Last update: **2022-05-08, 1401/02/18**

Update count: **0**

Registration date

2022-05-08, 1401/02/18

Registrant information

Name

maryam mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 0000

Email address

886maryammohammadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-10, 1401/02/20

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the efficacy of quadruple standard regimen combined with simvastatin, probiotic, and NAC as adjuvant therapy for H. Pylori eradication and comparing to standard treatment

Public title

Effect of simvastatin, probiotic and NAC drugs as adjuvant therapy to standard treatment in the eradication of Helicobacter pylori

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People over the age of 18 and under 65 With positive stool antigen test or endoscopy for Helicobacter pylori

Exclusion criteria:

History of heart, kidney and liver failure Diabetes
Developing an active cancer Drug and alcohol addiction
Recent history of gastrointestinal bleeding Get previous treatment

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **168****Randomization (investigator's opinion)**

Randomized

Randomization description

According to the method of permutation blocks, 8 people are divided into 2 groups completely randomly.

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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Chamran Highway, Yemen Street, Student Boulevard next to Taleghani Hospital

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2020-03-10, 1398/12/20

Ethics committee reference number

IR.SBMU.MSP.REC.1398.1001

Health conditions studied**1****Description of health condition studied**

Helicobacter pylori infection

ICD-10 code

B96.81

ICD-10 code description

Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes**1****Description**

Helicobacter pylori eradication rate

Timepoint

Beginning of the study and one month later

Method of measurement

Stool test for Helicobacter pylori antigen

Secondary outcomes

empty

Intervention groups**1****Description**

The standard four-drug protocol recipient group (metronidazole kimidaro 250 mg, amoxicillin-producing 1000 mg, pentaprazole kimidaro 40 mg and bismuth kimidaro 120 mg) all twice daily for 2 weeks.

Category

Treatment - Drugs

2**Description**

Intervention group: standard four drugs plus oral probiotic famiLact zist takhmir (250 mg daily) for 2 weeks.

Category

Treatment - Drugs

3

Description

Intervention group: standard four drugs plus simvastatin
Poursina (10 mg daily) for 2 weeks.

Category

Treatment - Drugs

4

Description

Intervention group: standard four drugs plus n-
acetylcysteine Avesina (600 mg daily) for 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Maryam Mohammadi

Street address

Imam Hossein hospital, Shahid Madani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zaraghi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice-chancellor in research affairs of Shahid Beheshti
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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elena Lak

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available