

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study of probiotic and simvastatin additive effect on Helicobacter eradication rate

Protocol summary

Study aim

Study of the effect of adding probiotic and simvastatin on eradication rate of Helicobacter pylori

Design

Individuals are divided into four groups based on random permutations, Patients and physicians do not know how to get people in groups.

Settings and conduct

In this study, people referred to the gastroenterology clinic of Imam Khomeini Hospital in Ahwaz who were confirmed by endoscopy and confirmed by Helicobacter pylori infection biopsy and not treated with Helicobacter pylori eradication were randomly divided into 4 groups. . Patients and physicians do not know how to get people in groups.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1. Be over 18 years old. 2. Satisfy. 3. Has been positive for H. pylori and has not received treatment until now. Exit criteria: 1. Lack of satisfaction 2. Have a history of recent antibiotic intake 3. Contra indications of probiotic or simvastatin intake or drug related drug use during drug use. 4. Alcohol consumption 5. Smoking

Intervention groups

1. The first group is a single dose of pantoprazole (40 mg bid), amoxicillin (1000 mg bid), clarithromycin (500 mg bid), bismuth (120 mg bid), and placebo once daily. 2. The second group received buprenorphine pantoprazole (40 mg bid), amoxicillin (1000 mg bid), clarithromycin (500 mg bid) and bismuth (120 mg bid) + probiotic (daily east 250 mg daily). 3. The third group received pantoprazole (40 mg bid), amoxicillin (1000 mg bid) and clarithromycin (500 mg bid) and bismuth (120 mg bid) + simvastatin (10 mg daily). 4. The fourth group is prescribed pantoprazole (40 mg bid), amoxicillin (1000 mg bid) and clarithromycin (500 mg bid) and bismuth (120 mg bid) + simvastatin (20 mg daily).

Main outcome variables

Comparison of Helicobacter pylori eradication in the

studied groups: Drug and Placebo - Drug + Probiotics - Drug + Simvastatin 10mg - Drug + Simvastatin 20mg

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180130038566N1**

Registration date: **2018-05-13, 1397/02/23**

Registration timing: **retrospective**

Last update: **2018-05-13, 1397/02/23**

Update count: **0**

Registration date

2018-05-13, 1397/02/23

Registrant information

Name

maryam biuseh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3292 1839

Email address

maryam.biuseh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2018-01-20, 1396/10/30

Trial completion date

empty

Scientific title

Study of probiotic and simvastatin additive effect on Helicobacter eradication rate

Public title

Eradication of Helicobacter

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Is over 18 years old. Is satisfied. In terms of Helicobacter pylori, it has not been treated until now.

Exclusion criteria:

Dissatisfaction. Have a history of recent antibiotic intake. Contra has indications of receiving probiotic or simvastatin, or when it comes to drug use during drug use. alcohol consumption. smoking.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **160**

Actual sample size reached: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the 8th permutation block method, individuals are randomly divided into 2 groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the group receiving the placebo capsule, 1 placebo tablet was given as simvastatin tablets and placebo. One group who received simvastatin tablets and placebo was given 1 placebo capsule similar to the probiotic capsule. The number and type of medication used in all groups was the same.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University

Street address

Ahvaz - Golestan - Jundishapur University of Ahvaz

City

ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-01-20, 1396/10/30

Ethics committee reference number

IR.AJUMS.REC.1396.892

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

Helicobacter pylori

ICD-10 code

B96.81

ICD-10 code description

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

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

Eradication rate of Helicobacter pylori

Timepoint

Patients are treated for two weeks, after which treatment is discontinued and four weeks after completion of the treatment, a fecal antigen test for eradication of Helicobacter pylori infection is examined.

Method of measurement

Measurement of Helicobacter pylori in Ahvaz Imam Khomeini Hospital Laboratory.

Secondary outcomes

empty

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

Simvastatin 10 mg - Sobhan Iran Co. - Required quantity or amount 560

Category

Treatment - Drugs

2**Description**

Simvastatin 20 mg - Sobhan Iran Co. - Required amount or amount of 560

Category

Treatment - Drugs

3

Description

Daily Probiotic - Bio-Fermentation Company - Iran
Manufacturing - Required Quantity or Required 560

Category

Treatment - Drugs

4

Description

Placebo - Pharmacy Company - Iran Manufacturing -
Required Quantity or Required 560

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Immunomotor Clinic Imam Khomeini Hospital

Full name of responsible person

Abazar Parsi

Street address

Imam Khomeini Hospital, Department of
Gastroenterology

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6193673111

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dr_abazar_parsi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Jundishapur University of Ahvaz, Deputy Director for
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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Abazar Parsi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Subspecialist

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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