Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 pentaprazole (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 pentaprazole (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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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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
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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