Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial comparing the effectiveness of probiotics along with standard three drug treatment and standard three drug treatment alone in eradicating Helicobacter pylori in dyspeptic patients between 15 and 45 years old with positive fecal antigen

Protocol summary

Study aim
Goal:the comparison of standard helicobacter pylori eradication regimen with and without using probiotics

Design
This study is a randomized clinical trial study. Subjects are told that they will be randomly assigned to one of these two 100-person groups.

Settings and conduct
In this study, which is carried out in the Madras hospital clinic, the control group of the standard treatment that includes antibiotics (amoxicillin 1 gram twice a day and clarithromycin 500 mg twice a day) and pantoprazole 40 mg twice a day and placebo twice a day for two will receive a week. In the control group, in addition to the standard treatment, lactocor is prescribed for two weeks. The outcome in this study is the presence of Helicobacter pylori, which is measured by the treatment success index. 4 weeks after the treatment, the amount of bacteria removal is evaluated through stool antigen test in both groups.

Participants/Inclusion and exclusion criteria
Entry criteria: age between 15-40 years; Verbal and written consent; symptoms of dyspepsia; Positive fecal Helicobacter pylori antigen test. Exclusion criteria: use of any antibiotic in the last 2 weeks; consumption of pump inhibitor during the last 1 month; History of any proven malignancy and history of receiving Helicobacter pylori eradication regimen at any time in the past

Intervention groups
In the test group, in addition to the standard treatment (amoxicillin 1 gram twice a day, clarithromycin 500 mg twice a day, and pantoprazole 40 mg twice a day), Lactobacillus and Bifidobacterium probiotic capsules are used for two weeks. In this study, the control group will receive standard and routine national treatment (amoxicillin 1 gram twice a day and clarithromycin 500 mg twice a day and pantoprazole 40 mg twice a day) along with placebo twice a day for two weeks.

Main outcome variables
Eradication of Helicobacter pylori infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221216056834N1**
Registration date: **2023-02-02, 1401/11/13**
Registration timing: **prospective**

Last update: **2023-02-02, 1401/11/13**
Update count: **0**

Registration date
2023-02-02, 1401/11/13

Registrant information

Name
Ramin Talaie

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2207 4100

Email address
r.talaie@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing the effectiveness of probiotics along with standard three drug treatment and standard three drug treatment alone in eradicating Helicobacter pylori in dyspeptic patients between 15 and 45 years old with positive fecal antigen

Public title

The effectiveness of probiotics in eradicating Helicobacter pylori infection of the stomach

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 15-40 years Verbal and written consent symptoms of dyspepsia Positive fecal Helicobacter pylori antigen test.

Exclusion criteria:

use of any antibiotic in the last 2 weeks consumption of pump inhibitor during the last 1 month History of any proven malignancy history of receiving Helicobacter pylori eradication regimen at any time in the past.

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, people are placed in groups using the block blinding method, so that first blocks of 4 are prepared in the form of AABB, ABAB, ABBA, BBAA, BABA, BAAB, and then these blocks are arranged randomly. And people are assigned to two groups according to A and B, and this work is repeated continuously. The website www.sealedenvelope.com is used to generate a random sequence for block randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is of double-blind type. Blinding for both the participants and the researcher will be done using the identical appearance of the drugs, which will be done by the drug manufacturing company.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Medicine - Shahid Beheshti University of Medical Sciences (Research Ethics Committee)

Street address

Tehran - Velenjak - Shahid Beheshti University of Medical Sciences - Faculty of Medicine

City

tehran

Province

Tehran

Postal code

198396941

Approval date

2022-10-18, 1401/07/26

Ethics committee reference number

IR.SBMU.MSP.REC.1401.315

Health conditions studied

1

Description of health condition studied

Helicobacter pylori infection in dyspeptic patients

ICD-10 code

B96.81

ICD-10 code description

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

Primary outcomes

1

Description

Fecal antigen

Timepoint

one month after the end of the intervention

Method of measurement

elisa test

Secondary outcomes

1

Description

Digestive complications

Timepoint

1 month after the end of the intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Control group: allocation of the standard treatment regimen alone (i.e. pentaprazole 40 mg (b.i.d), amoxicillin 1000 mg (b.i.d), clarithromycin 500 mg (b.i.d)) for 14 days along with a capsule similar to the probiotic capsule without any medicinal properties Made by a contracted pharmacist that is given exactly like probiotic capsules for 2 weeks from the start of the standard regimen.

Category

Treatment - Drugs

2

Description

Intervention group: treatment with three standard drugs (i.e., pentaprazole 40 mg (b.i.d), amoxicillin 1000 mg (b.i.d), clarithromycin 500 mg (b.i.d)) for 14 days along with probiotic capsules made by Bio Fermentation Company (Lactocer). Contains lactobacillus acidophilus and bifidobacterium bifidum, given twice a day from the day the treatment starts for up to 2 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Superspeciality Clinic of Modares Hospital in Tehran

Full name of responsible person

Ramin Talaie

Street address

End of Saadat Abad Street - Intersection of Imam Memorial Highway and Saadat Abad

City

Tehran

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Tehran

Postal code

1998734383

Phone

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Fax

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Email

modarres@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behrouz Abtahi

Street address

Tehran - Evin - Shahid Shahriari Square - Shahid Beheshti University Research and Technology Vice-Chancellor

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1983969411

Phone

+98 21 29901

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pr-office@sbu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Ramin Talaie

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ramin Talaie
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Person responsible for updating data

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Associate Professor
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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Students and researchers can use the data of this study
From where data/document is obtainable
Researchers can contact the author of the study through r.talaie@sbmu.ac.ir to receive data and information.
What processes are involved for a request to access data/document
Researchers can contact the author of the study through r.talaie@sbmu.ac.ir to receive data and information.
Comments