

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the impact of probiotic supplementation on the efficacy of therapy in eradicating *Helicobacter pylori*

Protocol summary

Study aim

Evaluation of the impact of probiotic supplementation on the efficacy of therapy in eradicating *Helicobacter pylori*

Design

This is a double-blind, randomized clinical trial with a parallel design and a control group. This randomized study, phases 2-3, will be conducted on 120 patients with *Helicobacter pylori*. A random block design is used for randomization, and the participants are assigned to two intervention and control groups.

Settings and conduct

This study, which will be conducted at Imam Reza Hospital of Kermanshah, is double-blinded. The patients are aware of participating in the study and receiving the new drug, but the researcher and the participant will be kept blind to which group will receive the new drug and which group will receive the placebo. The beginning of the study, benefits, and side effects. The possibility of probiotic treatment is explained to patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Dyspepsia symptoms for at least six months or more Exclusion criteria: History of kidney failure; Patients with a history of taking any antibiotics during the last month and a history of taking proton pump inhibitors and antacids in the last week; Consumption of alcohol or drugs or non-steroidal anti-inflammatory drugs

Intervention groups

The intervention group was given a standard four-drug regimen against *Helicobacter* (one gram of amoxicillin, 250 mg of metronidazole, 300 mg of bismuth, and 40 mg of pantoprazole) for ten days along with two probiotic tablets daily every twelve hours for Four weeks follow. The placebo group also received the regimen of four standard anti-helicobacter drugs (Same as the intervention group) for ten days and placebo capsules two tablets daily every twelve hours for Four weeks follow.

Main outcome variables

Helicobacter pylori infection rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N191**

Registration date: **2022-12-21, 1401/09/30**

Registration timing: **prospective**

Last update: **2022-12-21, 1401/09/30**

Update count: **0**

Registration date

2022-12-21, 1401/09/30

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-04-04, 1402/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the impact of probiotic supplementation on the efficacy of therapy in eradicating *Helicobacter pylori*

Public title

The effect of probiotic supplementation on the effectiveness of stomach infection treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent dyspepsia symptoms for at least 6 months or more

Exclusion criteria:

History of kidney failure Patients with a history of taking any antibiotics during the last month and a history of taking proton pump inhibitors and antacids in the last week. Patients with stomach tumors Consumption of alcohol or drugs or non-steroidal anti-inflammatory drugs Having an endoscopic pattern of gastritis Family history of gastrointestinal disease and anti-*Helicobacter pylori* treatment regimen

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Using 12 random blocks that will be created using the website <https://www.sealedenvelope.com>, the samples are studied in each of the groups. The researcher responsible for collecting information is unaware of the type of allocation of samples to the study groups. Coding is done by one of the collaborators of the project. So that a) 12 blocks are considered. b) An English letter is assigned to each of the groups: A to the intervention group, B to the placebo group c) A sequence will be created for a sample size of 120. d) For the random allocation concealment process, ten opaque envelopes (10 constructed blocks) and 120 cards (the size of the total sample) will be made. Inside each envelope, 12 cards will be placed in the sequence in each block. Block numbers were written on each envelope. The name of the desired group will be written on each card in sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind; in this way, the participant is not aware of his allocation to the probiotic treatment

group or the placebo group; in addition, the researcher is unaware of the members of the two groups. Each dose of medicine is individually packaged and has an identification number. Vials and boxes of medicine and placebo are supplied in completely similar appearance and packaging, which will cause blinding of the participants and the researcher.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2022-09-18, 1401/06/27

Ethics committee reference number

IR.KUMS.MED.REC.1401.122

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

Helicobacter pylori Infection

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

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

Helicobacter pylori infection rate

Timepoint

At the beginning of the study and six weeks after the start of the study

Method of measurement

Using the lateral flow technique

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group was given a standard four-drug regimen against *Helicobacter* (one gram of amoxicillin, 250 mg of metronidazole, 300 mg of bismuth, and 40 mg of pantoprazole) for ten days along with two probiotic tablets (Rist Fermentation Company) daily every twelve hours for Four weeks follow.

Category

Treatment - Drugs

2

Description

The placebo group also received the regimen of four standard anti-helicobacter drugs (One gram of amoxicillin, 250 mg of metronidazole, 300 mg of bismuth, and 40 mg of pantoprazole) for ten days and placebo capsules (Rist Fermentation Company) two tablets daily every twelve hours for Four weeks follow.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Eideh Ramezani Ghanbari

Street address

Emam Reza Hospital, Parastar Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Cyrus Jalili

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Eideh Ramezan Ghanbari

Position

Internal resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Homayoon Bashiri

Position

Member of the academic staff of Kermanshah University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Digestion

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Person responsible for updating data

Contact

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Position

Internal resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available