Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 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)

Phone
+98 83 1821 4653

Email address
fforoughi@kums.ac.ir

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

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3427 4618

Email
eidehghambari63@gmail.com

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

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3836 0014

Email
cjalili@kums.ac.ir

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

Street address
Emam Reza Hospital, Parastar Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3427 4618

Email
eidehghambari63@gmail.com

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

Street address
Emam Reza Hospital, Parastar Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3427 4618

Email
hbashirimd@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Eideh Ramezani Ghanbari

Position
Internal resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
Emam Reza Hospital, Parastar Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3427 4618

Email
eidehghambari63@gmail.com

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