Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of probiotic composition on the treatment regimen of four drugs for Helicobacter pylori infection

Protocol summary

Study aim
Determining the effect of probiotic composition on the treatment regimen of four drugs for Helicobacter pylori infection

Design
A clinical trial with a control group, with parallel groups, double-blind, on 200 patients, Randomized by the method of Balanced Block Randomization

Settings and conduct
The present parallel randomized clinical trial will be conducted on 200 patients referred to Qazvin Velayat hospital with complaints of dyspepsia or serious digestive problems with a positive Helicobacter pylori test through positive fecal antigen or positive biopsy sample. After entering the study, the participants are randomly assigned to two intervention and control groups using random blocks (20 blocks of ten). Patients, clinical caregivers, and analysts are blinded. Patients undergo drug treatments for two weeks. To confirm the eradication, a stool antigen test is taken 4 weeks after stopping the treatment. Also, possible side effects are investigated by questions and clinical examination.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Helicobacter pylori infection; Age 18 to 75 years Exclusion criteria: failure to complete the consent form; stomach cancer; kidney and liver failure; pregnancy and breastfeeding; History of gastric surgery

Intervention groups
1- Common treatment of Helicobacter along with Femi Lact probiotic including Oral metronidazole 500 mg / Oral bismuth 300 mg / Oral amoxicillin 500 mg / Oral omeprazole 40 mg / Familact probiotic capsule 500 mg for 14 days 2- Common treatment of Helicobacter including Oral metronidazole 500 mg / Oral bismuth 300 mg / Oral amoxicillin 500 mg / Oral omeprazole 40 mg for 14 days

Main outcome variables
Fecal antigen test; Stomach ache; Burning in the stomach; Pain in the affected area under the ribs and above the navel

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240222061080N1**
Registration date: **2024-02-28, 1402/12/09**
Registration timing: **prospective**

Last update: **2024-02-28, 1402/12/09**
Update count: **0**

Registration date
2024-02-28, 1402/12/09

Registrant information

Name
Najmeh Khalili Naft Chali

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3379 0620

Email address
zahra.ahangarii7@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-03, 1403/01/15

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of probiotic composition on the treatment regimen of four drugs for Helicobacter pylori infection

Public title
Investigating the effect of probiotics in the treatment of Helicobacter pylori infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Helicobacter pylori infection Age 18 to 75 years
Exclusion criteria:
Gastric cancer Kidney and liver failure History of gastric surgery Pregnancy and breastfeeding Unwillingness to participate in the study
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of random assignment in this study is Balanced Block Randomization. 20 blocks of 10 A, B are numbered from 1 to 10 and numbers 1 to 10 are selected from the table of random numbers and placed together. Then they are replaced with numbered blocks
Blinding (investigator's opinion)
Double blinded
Blinding description
The clinical caregiver receives the drugs that are coded in closed envelopes and injects them into the patients. Coding is done by one of the collaborators of the project. The clinical caregiver, the participant and the analyst are blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Research and Technology deputy, 1st Branch, Maudet Alley, Shahid Beheshti Blvd, Qazvin
City
Qazvin
Province
Qazvin
Postal code
3415613911
Approval date
2024-02-18, 1402/11/29
Ethics committee reference number
IR.QUMS.REC.1402.370

Health conditions studied

1

Description of health condition studied
Patients with Helicobacter pylori infection
ICD-10 code
B96.81
ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
The recurrence rate of Helicobacter pylori in patients
Timepoint
4 weeks after treatment
Method of measurement
Fecal antigen test

Secondary outcomes

1

Description
The incidence of complications and improvement of clinical symptoms in patients
Timepoint
4 weeks after the end of the intervention
Method of measurement
Clinical examination in terms of pain or burning in the abdomen and the affected area below the ribs and above the navel

Intervention groups

1

Description
Intervention group: Oral metronidazole 500 mg four times a day / Oral bismuth 300 mg four times a day / Oral amoxicillin 500 mg four times a day / Oral omeprazole 40 mg twice a day / Familact probiotic capsule (Biz Pharmaceutical Company) fermentation) 500 mg twice a day for 14 days
Category
Treatment - Drugs

2

Description
Control group: Oral metronidazole 500 mg four times a day / Oral bismuth 300 mg four times a day / Oral amoxicillin 500 mg four times a day / Oral omeprazole 40 mg twice a day for 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Najmeh Khalili Naft Chali
Street address
Tavon Square, 22 Bahman Blvd, Elahiye Quay, Minodar Town
City
Qazvin
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34719-76161
Phone
+98 28 3379 0620
Email
najmeh.khalili2016@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Seyed Mahidi Mirhashemi
Street address
Research and Technology deputy, Mavaddat Alley, Shahid Beheshti Blvd, Qazvin
City
Qazvin
Province
Qazvin
Postal code
34199-15315
Phone
+98 28 3333 6001
Email
clinical_research@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Najmeh Khalili Naft Chali
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Tavon Square, 22 Bahman Blvd, Elahiye Quay, Minodar Town
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Person responsible for scientific inquiries

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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