

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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

Province

Qazvin

Postal code

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

Street address

Tavon Square, 22 Bahman Blvd, Elahiye Quay, Minodar Town

City

Qazvin

Province

Qazvin

Postal code

34719-76161

Phone

+98 28 3379 0620

Email

najmeh.khalili2016@gmail.com

Person responsible for scientific 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

Street address

Tavon Square, 22 Bahman Blvd, Elahiye Quay,
Minodar Town

City

Qazvin

Province

Qazvin

Postal code

34719-76161

Phone

+98 28 3379 0620

Fax

Email

najmeh.khalili2016@gmail.com

Person responsible for updating data

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

Street address

22 Bahman Blvd, Tavon Square, Elahiye Quay,
Minodar Town

City

Qazvin

Province

Qazvin

Postal code

34719-76161

Phone

+98 28 3379 0620

Fax

Email

najmeh.khalili2016@gmail.com

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