

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the Effectiveness of Treatment by piloshot Probiotic and Standard Quadruple Regimen in Patients with Helicobacter Pylori

Protocol summary

Eradicate Helicobacter pylori infection, drug side effects, clinical symptoms after treatment

Study aim

Evaluating the Effectiveness of Treatment by piloshot Probiotic and Standard Quadruple Regimen in Patients with Helicobacter Pylori

Design

The present study will be performed as a randomized clinical trial on patients with symptomatic HP infection. Patients enter the study after obtaining informed consent and will be randomly divided into two groups of 100 intervention and control who will be matched in terms of demographic conditions. None of the patients can choose between placebo or probiotic and the conditions will be the same for both groups.

Settings and conduct

HP infection can be confirmed by examining tissue samples from endoscopy and urease test. The duration of treatment will be 14 days. Patients will not take any medication for up to a month after treatment and will be followed up for HP eradication. Stool antigen test is used to follow patients in a fixed laboratory

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infection with HP based on urease test on endoscopic tissue samples, Age over 18 years, Indications for HP eradication treatment, Satisfaction to enter the project and perform endoscopy. Exclusion criteria: Dissatisfaction with participating in the project, Dissatisfaction or possibility of endoscopy, No endoscopic indication, History of treatment failure, History of drug allergy or contraindication to amoxicillin, clarithromycin and bismuth, Take another herbal medicine or probiotic at the same time

Intervention groups

The intervention group will be treated with a four-drug regimen including amoxicillin, clarithromycin, bismuth, pantoprazole with 2 piloshot probiotic capsules daily and the control group will be treated with the above-mentioned four drug regimen with 2 piloshot placebo capsules daily

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210719051943N2**

Registration date: **2022-03-06, 1400/12/15**

Registration timing: **prospective**

Last update: **2022-03-06, 1400/12/15**

Update count: **0**

Registration date

2022-03-06, 1400/12/15

Registrant information

Name

mehdi pezeski modares

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3612 2000

Email address

mpezeskim@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effectiveness of Treatment by piloshot Probiotic and Standard Quadruple Regimen in Patients with Helicobacter Pylori

Public title

Eradicate Helicobacter pylori infection

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infection with Helicobacter pylori based on urease test results on endoscopic tissue samples Age over 18 years Indications for Helicobacter pylori eradication treatment Satisfaction to enter the project and perform endoscopy

Exclusion criteria:

Dissatisfaction with participating in the project Dissatisfaction or possibility of endoscopy No endoscopic indication History of treatment failure History of drug allergy or contraindication to amoxicillin, clarithromycin and bismuth Take another herbal medicine or probiotic at the same time

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method will be used and the block size is 4. Considering our sample size equal 200, we used 50 blocks. The selection among 6 possible blocks will be conducted based on simple random sampling. 6 possible blocks are including AABB, ABAB, BBAA, BABA, ABBA, BAAB

Blinding (investigator's opinion)

Double blinded

Blinding description

After completing the entry criteria and obtaining informed consent, patients are referred to a caregiver to receive medication. At this stage, the caregiver accidentally gives the patient drug packages that include groups A and B. The patient, the researcher, and the caregiver have no say in the selection. After completing the treatment process by patients and follow-up to eradicate, the examination begins as to which patient has taken which drug. Thus, none of the groups of researchers, participants and caregivers are involved in the choice of treatment

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Qom University of Medical Sciences

Street address

Beheshti Blvd. Shahid Beheshti Hospital

City

Qom

Province

Ghous

Postal code

3719964797

Approval date

2022-01-02, 1400/10/12

Ethics committee reference number

IR.MUQ.REC.1400.202

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

Helicobacter Pylori

ICD-10 code

B96.81

ICD-10 code description

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

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

Eradicate Helicobacter pylori infection

Timepoint

Patients in the intervention group underwent a four-drug regimen for Helicobacter pylori eradication, including amoxicillin capsules plus clarithromycin capsules and bismuth tablets plus pantoprazole, plus 2 capsules piloshot daily, and patients in the control group will be treated with the above four-drug regimen along with 2 placebo tablets of Pilochat drug daily. The duration of the treatment period will be 14 days. Helicobacter pylori will be followed up after treatment

Method of measurement

Bacterial fecal antigen test

2

Description

Drug side effects

Timepoint

Patients in the intervention group underwent a four-drug regimen for Helicobacter pylori eradication, including amoxicillin capsules plus clarithromycin capsules and bismuth tablets plus pantoprazole, plus 2 capsules piloshot daily, and patients in the control group will be treated with the above four-drug regimen along with 2 placebo tablets of Pilochat drug daily. The duration of the treatment period will be 14 days. Helicobacter pylori will be followed up after treatment

Method of measurement

questionnaire

3

Description

Clinical symptoms after treatment

Timepoint

Patients in the intervention group underwent a four-drug regimen for Helicobacter pylori eradication, including amoxicillin capsules plus clarithromycin capsules and bismuth tablets plus pantoprazole, plus 2 capsules piloshot daily, and patients in the control group will be treated with the above four-drug regimen along with 2 placebo tablets of Pilochat drug daily. The duration of the treatment period will be 14 days. Helicobacter pylori will be followed up after treatment

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients in the control group will be treated with the four-drug regimen of two capsules of amoxicillin 500 every 12 hours, one clarithromycin 500 capsules every 12 hours, one pantoprazole 40 every 12 hours, two bismuth tablets every 12 hours with 2 placebo of piloshot daily (contains lactose mesh 200, ac-di-sol, talc, colloidal silicon dioxide and magnesium stearate)

Category

Treatment - Drugs

2

Description

Intervention group: :Patients in the intervention group under the helicobacter pylori eradication will be treated with four-drug regimen, including two capsules of amoxicillin 500 every 12 hours plus one clarithromycin 500 capsules every 12 hours and two bismuth tablets every 12 hours plus one pantoprazole 40 every 12 hours will be accompanied by 2 capsules of Pilochet (containing

Lactobacillus ruteri, casei ,Acidophilus and Bifidobacterium) daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mehdi Pezeshki Modares

Street address

Beheshti Blvd. Shahid Beheshti Hospital

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Email

mpezeshkim@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Ehsan Sharifipour

Street address

Safashar

City

Qom

Province

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3719964797

Phone

+98 25 3285 4011

Email

Ehsansharifipour@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Mahdi Pezeshki Modares

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mehdi Pezeshki Modares

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mehdi Pezeshki Modares

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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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

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data can be shared after people have not been identified

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used

According to the rules of the COPE

From where data/document is obtainable

mpezeshkim@gmail.com

What processes are involved for a request to access data/document

By email the responsible author(mpezeshkim@gmail.com)

Comments