Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

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

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

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 pezeshki modares

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3612 2000

Email address

mpezeshkim@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
Ghoum

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
City
Qom
Province
Ghoum
Postal code
3719964797
Phone
+98 25 3612 2526
Email
mpezeshkim@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Ehsan Sharifipour
Street address
Safashar
City
Qom
Province
Ghoum
Postal code
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
Ghoum 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

Ghoum 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

Street address

Beheshti Blvd. Shahid Beheshti Hospital

City

Qom

Province

Ghoum

Postal code

3719964797

Phone

+98 25 3612 2526

Email

mpezeshkim@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

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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City

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Phone

+98 25 3612 2000

Email

mpezeshkim@muq.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ghoum University of Medical Sciences

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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City

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Province

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Postal code

3719964797

Phone

+98 25 3612 2000

Email

mpezeshkim@muq.ac.ir

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