Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Assessment effect of Lactobacillus Reuteri (pyloshot) in H.pylori eradication with clarithromycin, amoxicillin and pantoprazole

Protocol summary

Study aim
Assessment effect of Lactobacillus Reuteri (pyloshot) in H.pylori eradication with clarithromycin, amoxicillin and pantoprazole

Design
This study is a phase 3 parallel randomized clinical trial. . Individuals are told that they are randomly assigned to one of these two groups of 38 people.

Settings and conduct
In this study, the control group will receive standard and routine treatment consisting of two antibiotics (amoxicillin 1 gr twice daily and clarithromycin 500 mg twice daily), pantoprazole 40 mg twice daily, and placebo twice daily for two weeks. In the case group, in addition to standard treatment, pilots are prescribed for two weeks. In this study, patients in the case group used calcium, magnesium and zinc in the form of pilot capsules in addition to Lactobacillus and Bifidobacterium probiotics. The outcome of this study is the presence of Helicobacter pylori, which is measured by the treatment success index. Outcomes of treatment 4 weeks after treatment, the rate of bacterial eradication in both groups is evaluated. The success rate of treatment is assessed by screening for Helicobacter pylori antigen and the rate is assessed by a stool test.

Participants/Inclusion and exclusion criteria
1- Have Helicobacter pylori. 2- The patient volunteering to participate in the study, 3- Age 40-75 years 4- Be a resident of Arak.

Intervention groups
In the case group, in addition to standard treatment (amoxicillin 1 gr twice daily and clarithromycin 500 mg twice daily and pentoprazole 40 mg twice daily) for two weeks, Lactobacillus and Bifidobacterium probiotic capsules are used twice daily. In this study, the control group will receive standard and national treatment (amoxicillin 1 gr twice daily, clarithromycin 500 mg twice daily, and pantoprazole 40 mg twice daily) with placebo twice daily for two weeks.

Main outcome variables
Eradication of Helicobacter pylori infection

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201225049825N1**
Registration date: **2021-02-12, 1399/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-12, 1399/11/24**
Update count: **0**

Registration date
2021-02-12, 1399/11/24

Registrant information
Name
Zahra Hashemi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 86 3368 3717
Email address
drhashemiz2018@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-01-20, 1399/11/01
Expected recruitment end date
2021-06-22, 1400/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment effect of Lactobacillus Reuteri (pyloshot) in H.pylori eradication with clarithromycin, amoxicillin and pantoprazole

Public title
Evaluation of the effect of Lactobacillus ruteri in the treatment of Helicobacter pylori with clarithromycin, pantoprazole and amoxicillin regimen

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Have Helicobacter pylori The patient volunteering to participate in the study, Age 40-75 years Be a resident of Arak.

Exclusion criteria:
Having a metastatic cancer Pregnancy Breastfeeding History of failure of previous H.PYLORI treatment Incomplete prescribed treatment regimen Irregular use of medications and non-adherence to the prescribed treatment regimen Previous gastrectomy Suffering from incurable diseases Patients with IHD Chronic renal failure GI bleeding Malignancy Concomitant use of tetracycline, quinolone, bisphosphonates, and levothyroxine (drug interaction) People undergoing chemotherapy Short Bowel Syndrome Anemia and neutropenia fever History of drug and food allergies Hypercalcemia

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, individuals were divided into groups by block blinding method so that first 4 blocks were prepared as AABB and ABAB, ABBA, BBAA, BABA, BAAB and then these blocks were randomly arranged and individuals According to A and B, they were assigned to two groups and this was repeated continuously.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind study. Blinding will be done for both participants and the researcher using the same appearance of the drugs, which will be done by the drug company.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
University of Medical Sciences, Payambar Azam University Complex. Deputy of research and technology

City
Arak

Province
Markazi

Postal code
3848176341

Approval date
2020-09-16, 1399/06/26

Ethics committee reference number
IR.ARAKMU.REC.1399.175

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Helicobacter pylori infection using fecal antigen test

Timepoint
At the beginning of the study and 4 weeks after the intervention

Method of measurement
Stool antigen test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, in addition to the

standard and routine treatment , which includes two antibiotics (amoxicillin one gram twice a day and clarithromycin five hundred mg twice a day) and pantoprazole 40 mg twice a day, pilochat is prescribed for two weeks. In this study, patients in the experimental group used calcium, magnesium and zinc in the form of pilot capsules in addition to Lactobacillus and Bifidobacterium probioticsprobiotics.

Category

Treatment - Drugs

2

Description

Control group: In this study, the control group will receive standard treatment (amoxicillin 1 gr twice daily, clarithromycin 500 mg twice daily, and pantoprazole 40 mg twice daily) with placebo twice daily for two weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital, Arak

Full name of responsible person

Zahra Hashemi

Street address

Amir Al-Momenin Hospital, Next to the School of Medicine, Basij Square (Sardasht), Arak

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it-amiralmomenin@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Finance Management, Third Floor, Arak University of Medical Sciences, Alma Al-Huda St., Shahid Shiroodi St.

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dopdarman@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Zahra Hashemi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Laleh Alley 8, Hafezieh Boulevard, Hafezieh Town

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Students and researchers can use the data of this study.
From where data/document is obtainable
Researchers can contact the study author via email at Drhashemiz2018@gmail.com to receive data and information.
What processes are involved for a request to access data/document
Request information and data to the author via email Drhashemiz2018@gmail.com
Comments