

# 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 pantoprazole 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

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3417 3601

##### Email

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.

##### City

Arak

##### Province

Markazi

##### Postal code

۳۸۱۹۶۹۳۳۴۰

##### Phone

+98 86 3312 4955

##### Email

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

##### City

Arak

##### Province

Markazi

##### Postal code

۳۸۱۸۶۶۵۵۶۷

##### Phone

+98 86 3368 3717

##### Email

Drhashemiz2018@gmail.com

## Person responsible for scientific 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

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Drhashemiz2018@gmail.com

**Person responsible for updating data****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**

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**Email**

Drhashemiz2018@gmail.com

**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**