

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of Quadruple Therapy with *Saccharomyces Boulardii* or a *Lactobacillus Reuteri* Strain DSMZ 17648 Supplement (PYLOSHOT®) on Eradication of *Helicobacter Pylori* and Treatment Side Effects: a Double-Blind Placebo-Controlled Randomized Clinical Trial

Protocol summary

Study aim

Evaluate the effect of adding probiotic *Saccharomyces Boulardii* (DAILY EAST) or DSMZ 17648 *Lactobacillus Reuteri* strain supplement (PYLOSHOT), to the four-drug standard treatment after 14 days for *H. Pylori* infection, on increasing the elimination rate and reducing side effects.

Design

Of the patients with complete consent and inclusion criteria, 156 patients were selected as available. Then, using the oblique coin, patients are randomly assigned to treatment groups of 52 people. The clinical trial has a control group, with parallel groups, double-blind and randomized.

Settings and conduct

The study site is the specialty gastrointestinal clinic of Valiasr hospital in Birjand. The 156 patients were randomly divided into 52 groups (one control group and two case groups). The control group received placebo for 14 days with a routine anti-*Helicobacter pylori* quadruple regimen. Case groups are treated with DAILYEAST® or PHYLOSHOT supplement for 14 days.

Participants/Inclusion and exclusion criteria

Symptomatic *H. pylori*-positive individuals, confirmed by clinical, endoscopic, and pathological reports, are the inclusion criteria. Under 15 years of age, history of any concomitant serious illness, immunosuppressive drug use, antibiotic use in the past 3 months, and proton pump inhibitors, bismuth salts, or probiotics over the past 4 weeks, history of gastric surgery, clear weight loss, Previous history of *Helicobacter pylori* eradication, alcohol or drug abuse, and concurrent clinical trials are all excluded.

Intervention groups

Probiotics generally have potential beneficial effects in the treatment and prevention of various gastrointestinal

diseases. *Saccharomyces Bullardi* (DAILYEAST® supplement) and DSMZ 17648 *Lactobacillus Reuteri* (PYLOSHOT supplement) are the most common probiotics used in clinical trials.

Main outcome variables

Stool Antigen test; Recovery time; Treatment complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200106046021N1**

Registration date: **2020-01-14, 1398/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-14, 1398/10/24**

Update count: **0**

Registration date

2020-01-14, 1398/10/24

Registrant information

Name

Nushin Naghibzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3162 2035

Email address

nushin_naghibzadeh@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-08, 1398/10/18

Expected recruitment end date

2020-07-08, 1399/04/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Quadruple Therapy with Saccharomyces Boulardii or a Lactobacillus Reuteri Strain DSMZ 17648 Supplement (PYLOSHOT®) on Eradication of Helicobacter Pylori and Treatment Side Effects: a Double-Blind Placebo-Controlled Randomized Clinical Trial

Public title

The effect of Quadruple Therapy with Saccharomyces Boulardii or a Lactobacillus Reuteri Strain DSMZ 17648 Supplement (PYLOSHOT®) on Eradication of Helicobacter Pylori and Treatment Side Effects

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Symptoms of H. pylori-positive as Confirmed by Clinical, Endoscopic, and Pathological Reports.

Exclusion criteria:

Pregnancy and lactation Patients with Liver, CardioPulmonary, Renal, Neoplastic Diseases People taking Proton Pump Inhibitors, Bismuth Salts, or Probiotics for the past 4 weeks and any Immuno Suppressive Drugs Surgery such as Gastrectomy or Gastric Bypass The existence of Autoimmune Diseases IBD (Inflammatory Bowel Disease) Organ Transplant Weight loss over 3kg over the past three months Previous History of Helicobacter Pylori Eradication Oral Antibiotic use in less than 3 months Alcohol abuse Participate in Other Clinical Trials Concurrently

AgeFrom **15 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **156**

More than 1 sample in each individual

Number of samples in each individual: **2**

Helicobacter Pylor Stool Antigen Testing will be

Performed for Patients 2 and 6 weeks after treatment.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are selected as Available and then Randomly Assigned to Treatment Groups using the Oblique Coin.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, All Participants, Physicians Responsible for Treating Patients, the Principal Investigator, and the Collectors of Patient information and data on outcome variables, Blinding be.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Birjand University of Medical Sciences

Street address

Second floor, Valiasr Hospital, Ghaffari Ave., Department of Education

City

Birjand

Province

South Khorasan

Postal code

971783577

Approval date

2020-01-05, 1398/10/15

Ethics committee reference number

IR.BUMS.REC.1398.305

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

Gastric infection with Helicobacter pylori

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Mean recovery time in study groups

Timepoint

2 and 6 weeks after the end of treatment

Method of measurement

Stool Antigen Test

2

Description

Frequency distribution of treatment side effects in study groups

Timepoint

During treatment weekly

Method of measurement

Using the questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Taking placebo capsules that are completely identical to supplements in weight, size, shape and taste for 14 days in combination with the standard four-dose regimen for Helicobacter pylori infection for 14 days. The dosage is one after breakfast and one after dinner.

Category

Placebo

2

Description

First Intervention group: They take supplemental Saccharomyces Bullardi (DAILYEST®) for 14 days in combination with the usual four-dose regimen for Helicobacter pylori infection, one after breakfast and one after dinner.

Category

Treatment - Drugs

3

Description

Second Intervention group: Supplement DSMZ 17648 Lactobacillus Reuteri (PYLOSHOT) strain for 14 days in combination with routine quadruple therapy for Helicobacter pylori infection, two after breakfast and two after dinner.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Nushin Naghibzadeh

Street address

Ghaffari Street, Valiasr Hospital

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Birjand

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Birjand University of Medical Sciences

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Ghafari Street, Central Organization of Birjand University of Medical Sciences

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

40

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

2

Sponsor

Name of organization / entity

ZIST TAKHMIR Pharmaceutical company

Full name of responsible person

Dr. Mojgan Velayati

Street address

Resalat Square, Farjam Street, Heidarkhani intersection, No. 597

City

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info@bonyankasra.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
ZIST TAKHMIR Pharmaceutical company
Proportion provided by this source
60
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Nushin Naghibzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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9717853577
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nushin_naghibzadeh@bums.ac.ir

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

Age data of the participants, symptoms that led to the gastrointestinal clinic, the reason for the endoscopy, and the outcome after the end of the study were shared.

Participants are unrecognizable.

When the data will become available and for how long

Start access period immediately after printing results.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

If relevant, study compares the treatment regimens of *Helicobacter pylori* infection and the use of probiotics in treatment.

From where data/document is obtainable

Send mail to Dr. Tahmineh Tavakoli as a Clinical Trial Examiner. Birjand University of Medical Sciences.
tahminetavakoli95238@yahoo.com

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

Email and send request

Comments