

# 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

**Age**From **15 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**Target 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

##### **City**

Birjand

#### **Province**

South Khorasan

#### **Postal code**

9717853577

#### **Phone**

+98 56 3162 2035

#### **Email**

public\_r@bums.ac.ir

## **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

##### **Street address**

Ghafari Street, Central Organization of Birjand University of Medical Sciences

##### **City**

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##### **Province**

South Khorasan

##### **Postal code**

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##### **Phone**

+98 56 3239 5000

##### **Email**

public\_r@bums.ac.ir

#### **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**

Tehran  
**Province**  
Tehran  
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1683848411  
**Phone**  
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**Email**  
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**  
Internal Medicine  
**Street address**  
Second Floor, Valiasr Hospital, Ghaffari Ave., Department of Education  
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nushin\_naghibzadeh@bums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences  
**Full name of responsible person**  
Dr. Tahmine Tavakoli  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Gastroenterologist  
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Ghaffari Street, Valiasr Hospital  
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tahminetavakoli95238@yahoo.com

## Person responsible for updating data

### 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**  
Internal Medicine  
**Street address**  
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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**