

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of *Saccharomyces boulardii* as an adjunctive therapy in the eradication of *Helicobacter pylori*

Protocol summary

Study aim

The effect of *Saccharomyces boulardii* as an adjuvant therapy in the eradication of *Helicobacter pylori*

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 152 patients, randomization list through www.sealedenvelope.com/simple-randomiser/v1/lists

Settings and conduct

Patients with *Helicobacter pylori* infection referred to Shahid Beheshti hospital clinic in Kashan will be randomly divided to receive standard four-drug treatment + *Saccharomyces boulardii* probiotic or standard four-drug treatment for a period of two weeks.

Participants/Inclusion and exclusion criteria

Patients with *Helicobacter pylori* infection over 18 years of age referring to Shahid Beheshti Hospital in Kashan who have indication for treatment

Intervention groups

Intervention group: treated for fourteen days with a regimen of four drugs (pantaprazole 40 mg twice a day + amoxicillin 1 gram twice a day + clarithromycin 500 mg twice a day + bismuth 240 mg twice a day) + *Saccharomyces Boulardii* probiotic with the Sabolar brand (in the form of 250 mg capsules twice a day)
Control group: for fourteen days treated with a four-drug regimen (pantaprazole 40 mg twice a day + amoxicillin 1 gram twice a day + clarithromycin 500 mg twice a day + bismuth 240 mg twice a day)

Main outcome variables

Eradication of *Helicobacter pylori* (Stool Antibody test)

General information

Reason for update

According to most of the studies and Harrison's book (internal medicine reference), it is recommended to check the eradication of *Helicobacter pylori* after two weeks of finishing PPI drugs. Therefore, in the

measurement time section, the interval between the end of the PPI drug and checking the eradication of *Helicobacter pylori* from one week changed to two weeks. It should be noted that sampling has not been done yet.

Acronym

IRCT registration information

IRCT registration number: **IRCT20221025056290N1**

Registration date: **2022-11-03, 1401/08/12**

Registration timing: **prospective**

Last update: **2023-02-09, 1401/11/20**

Update count: **1**

Registration date

2022-11-03, 1401/08/12

Registrant information

Name

Vahid Kashanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5541 0386

Email address

kashanian-v@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-05, 1401/08/14

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of *Saccharomyces boulardii* as an adjunctive therapy in the eradication of *Helicobacter pylori*

Public title

The effect of *Saccharomyces boulardii* in the eradication of *Helicobacter pylori*

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with *Helicobacter pylori* infection

Exclusion criteria:

History of systematic and standardized eradication treatment
Kidney failure
Taking antibiotics in the last month
The person is pregnant and breastfeeding
History of neurological disease
Weakness in the immune system or taking immunosuppressive drugs

Age

From **19 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **152**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the intervention group was coded with the letter A and the control group with the letter B, and then using the website www.sealedenvelope.com/simple-randomiser/v1/lists randomization list was prepared by selecting a sample size of 152 (two groups of 76) and permuted block randomization method (block size=4) (38 blocks of 4). Then, through the obtained randomization list, the subjects included in the study will be assigned to one of the two groups, A or B. For example, suppose that in the first four blocks, the permutation method is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples to group B, and the same will continue until the last sample (152nd person).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Qutb Ravandi Boulevard - Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.117

Health conditions studied

1

Description of health condition studied

Helicobacter pylori disease

ICD-10 code

B98

ICD-10 code description

Helicobacter pylori [*H.pylori*] as the cause of diseases classified to other chapters

Primary outcomes

1

Description

Helicobacter pylori eradication

Timepoint

After one month of the last dose of antibiotics, and the patients have not taken PPI drugs for at least two week

Method of measurement

Fecal antigen test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For fourteen days, he was treated with a four-drug regimen (pantaprazole 40 mg twice a day + amoxicillin 1 gram twice a day + clarithromycin 500 mg twice a day + bismuth 240 mg twice a day) + *Saccharomyces Boulardi* probiotic under the Sabolar brand (in capsule form 250 mg twice daily)

Category

Treatment - Drugs

2

Description

Control group: For fourteen days, treated with a regimen of four drugs (pantaprazole 40 mg twice a day + amoxicillin 1 gram twice a day + clarithromycin 500 mg twice a day + bismuth 240 mg twice a day)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti Hospital Clinic

Full name of responsible person

Vahid Kashanian

Street address

Qutb Ravandi Boulevard, Shahid Beheshti Hospital

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beheshthospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Hamidi

Street address

Qutb Ravandi Blvd., University of Medical Sciences

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research@kaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Vahid Kashanian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Mohsen Razavizadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Vahid Kashanian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available