Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluating the effects of adding the probiotic Balance® compared with placebo to quadruple therapy on eradication of helicobacter pylori and symptoms of patients with peptic ulcer disease referring to gastroenterology clinics in Isfahan

Protocol summary

Summary

The aim of this study was to determine the effects of adding the probiotic Balance® to the quadruple therapy on eradication of helicobacter pylori and improvement of clinical symptoms in patients with peptic ulcer, referring to gastroenterology clinics of Isfahan. One hundred eighty adult patients with upper gastrointestinal symptoms (dyspepsia) referred to gastroenterologist that had endoscopic confirmed ulcers and helicobacter pylori infection by rapid urease test, and not having severe systemic disease or history of gastrointestinal surgery were included into the study. Patients were randomized into two groups (90 cases in each group) of Balance® and placebo. For all patients, quadruple therapy regimen (Omeprazole 20 mg twice daily, Bismuth subcitrate 240 mg twice daily, Amoxicillin 1 gr twice daily, and Clarithromycin 500 mg twice daily) were administered for 14 days. Patients in the Balance group received Balance® capsules twice daily (after dinner and lunch) for 14 days. In the placebo group, patients received placebo capsules the same as Balance® capsule. The main outcome was the helicobacter pylori eradication after 4 weeks and secondary outcome measures were dyspepsia symptoms assessed by the Lead Dyspepsia Questionnaire at baseline, end of treatment (day 15), and at the time of the evaluation of eradication (4 weeks after completion of therapy).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209041579N4**
Registration date: **2012-10-03, 1391/07/12**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2012-10-03, 1391/07/12

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of adding the probiotic Balance® compared with placebo to quadruple therapy on eradication of helicobacter pylori and symptoms of

patients with peptic ulcer disease referring to gastroenterology clinics in Isfahan

Public title
Probiotic for eradication of helicobacter pylori
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: - Age 18 to 65 years, - Having peptic ulcer disease on upper gastrointestinal endoscopy, - Having helicobacter pylori infection diagnosed by rapid urease test or urea breath test, - Willingness to participate in the study, - Not having Zollinger Ellison Syndrome, cancers of the digestive tract, liver or kidney diseases, other infections may require antibiotics, immune deficiency disease, - No history of upper gastrointestinal surgery, - No history of the eradication of Helicobacter pylori, or the use of Proton Pomp Inhibitors, antibiotics, and probiotics (synthetic or natural) over the past 4 weeks, - No contraindications for using any dug of the quadruple therapy. Exclusion criteria: - Not taking medications regularly, (not taking >= 20% of all the prescribed capsules), - Severe side effects of the quadruple therapy.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Patients were randomly assigned to two groups according to a table of random numbers created by the software. Placebo capsule was the same as Balance® capsule and both the physician and the patient were unaware about the treatment arms.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of Isfahan University of Medical Sciences
Street address
Vice Chancellor for Research, Isfahan University of Medical Sciences, Hezar Jarib Street
City
Isfahan
Postal code
Approval date
2011-07-10, 1390/04/19
Ethics committee reference number
390215

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection
ICD-10 code
B98.0
ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases classified

Primary outcomes

1

Description
Helicobacter pylori eradication
Timepoint
Four weeks after treatment
Method of measurement
Urea breath test

Secondary outcomes

1

Description
Dyspepsia symptoms severity
Timepoint
At baseline, 15th day, and 4 weeks after treatment
Method of measurement
Lead Dyspepsia Questionnaire

Intervention groups

1

Description
Intervention group: - Quadruple therapy regimen for helicobacter pylori eradication including Omeprazole 20 mg (Sobhan Co., Tehran, Iran) twice daily, Bismuth subcitrate 240 mg (ChemieDarou Co., Tehran, Iran) twice daily, Amoxicillin 1 gr (Farabi Co., Tehran, Iran) twice daily, and Clarithromycin 500 mg (Loghman Co., Tehran, Iran) twice daily for 14 days. Plus - Capsules of Balance® (Protexin Co., Somerset, UK) twice daily for 14 days. Each capsule of Balance® contains: Lactobacillus casei PXN 37 Lactobacillus rhamnosus PXN 54 Streptococcus

thermophilus PXN 66 Bifidobacterium breve PXN 25 Lactobacillus acidophilus PXN 35 Bifidobacterium longum PXN 30 Lactobacillus bulgaricus PXN 39. TVC per capsule: 100 million CFU

Category

Treatment - Drugs

2

Description

Control group: - Quadruple therapy regimen for helicobacter pylori eradication including Omeprazole 20 mg (Sobhan Co., Tehran, Iran) twice daily, Bismuth subcitrate 240 mg (ChemieDarou Co., Tehran, Iran) twice daily, Amoxicillin 1 gr (Farabi Co., Tehran, Iran) twice daily, and Clarithromycin 500 mg (Loghman Co., Tehran, Iran) twice daily for 14 days. Plus - Capsules of placebo twice daily for 14 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital Gastroenterology Clinics

Full name of responsible person

Dr. Elham Tabesh

Street address

Ferdosi Ave., Khorshid Hospital

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Peyman Adibi

Street address

Vice Chancellor for Research, Isfahan University of Medical Sciences, Hezar Jarib Street

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Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Elham Tabesh

Position

Physician, Resident of Internal Medicine

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty