Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Efficiency of Probiotic on Helicobacter Pylori Eradication, a Retrospective Parallel Group Double-Blind, Placebo-Controlled Randomized Clinical Trial

Protocol summary

Study aim
Evaluation of effect of probiotic on H. pylori eradication
Design
A parallel double-blind placebo-controlled trial, using computer package which generated random numbers, simple random allocation rule, with 100 participants.
Settings and conduct
Double-blind placebo-controlled trial, using labratory tests for evaluation of eradication,using symptoms questionnare.
Participants/Inclusion and exclusion criteria
Adult patients who their infection confirmed through histology, serum anti-H. pylori IgG, or stool antigen tests. The exclusion criteria were; taking antibiotics, bismuth component, proton pump inhibitor (PPI), and H2Blocker in the recent 2-3 months, pregnant women, patients with previous history of GI surgery, having concurrent severe disease during the time of experiment
Intervention groups
Treatment group should take probiotic, despite control group with taking placebo for two weeks.Both of them take this regimen; Omeprazole 20mg +Amoxicillin 1 gr + clarithromycin 500 mg twice daily, and with 6 weeks followed up study.
Main outcome variables
Finding new strategy or supplementation for eradication of this infection due to prevalence of drug therapy resistance and related side effects.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181015041349N1**
Registration date: **2019-02-09, 1397/11/20**
Registration timing: **retrospective**
Last update: **2019-02-09, 1397/11/20**
Update count: **0**
Registration date
2019-02-09, 1397/11/20

Registrant information
Name
Seyed Jalil Masoumi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3233 2771
Email address
ebrahimiv@sums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2015-05-21, 1394/02/31
Expected recruitment end date
2015-09-20, 1394/06/29
Actual recruitment start date
2015-06-21, 1394/03/31
Actual recruitment end date
2015-11-05, 1394/08/14
Trial completion date
2015-11-05, 1394/08/14

Scientific title
The Efficiency of Probiotic on Helicobacter Pylori Eradication, a Retrospective Parallel Group Double-Blind, Placebo-Controlled Randomized Clinical Trial

Public title
The Efficiency of Probiotic on Helicobacter Pylori Eradication
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with aged 18-63 years participants who their contamination were confirmed through histology, serum anti-H. pylori IgG, or stool antigen tests.

Exclusion criteria:

The exclusion criteria were taking antibiotics, bismuth component, proton pump inhibitor (PPI), and H2Blocker in the recent 2-3 months. Pregnant women as well as patients with previous history of GI surgery or having concurrent severe disease during the time of experiment also been excluded.

Age

From **18 years** old to **63 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was conducted using computer package which generated random numbers and group allocation was as well done by simple random allocation rule. Couples were randomly allocated into either probiotic (50 subjects, group A) or placebo (50 subjects, group B).

Blinding (investigator's opinion)

Double blinded

Blinding description

-

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz university of medical science

Street address

Zand avenue

City

Shiraz

Province

Fars

Postal code

7376116678

Approval date

2015-04-18, 1394/01/29

Ethics committee reference number

3901

Health conditions studied

1

Description of health condition studied

Effect of Probiotic on Eradication of H.pylori Infection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Eradication of H.pylori Infection

Timepoint

before intervention and 8 weeks later (after follow-up)

Method of measurement

histology, serum anti-H. pylori IgG, or stool antigen tests.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Probiotic (saccharomyces boulardii (250 mg, 1010 viable cells/g).Two weeks, twice per day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nemazee hospital

Full name of responsible person

Seyed Jalil Masoimi

Street address

Namazee Hospital- Zand Ave.- Namazee Square

City

Shiraz

Province

Fars

Postal code

7134874853

Phone

+98 71 3233 2313
Fax
+98 71 3233 2313
Email
massoumij@sums.ac.ir
Web page address
https://www.sums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Seyed Jalil Masoimi
Street address
Zand Ave.
City
Shiraz
Province
Fars
Postal code
7134874853
Phone
+98 71 3233 2313
Email
sjm@sums.ac.ir
Grant name
Grant code / Reference number
3901
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Seyed Jalil Masoumi
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Neshat Ave. Center for Information Technology Development
City
Shiraz
Province
Fars
Postal code
7134874853
Phone
+98 71 3233 2771
Email
sjm@sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Seyed Jalil Masoumi
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Neshat Ave. Center for Information Technology Development
City
Siraz
Province
Fars
Postal code
7134874853
Phone
+98 71 3233 2771
Email
sjm@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Vahid Ebrahimi
Position
Ph.D biostatistic student
Latest degree
Master
Other areas of specialty/work
Biostatistics
Street address
Biostatistic Center, Medical School, Zand Ave.
City
Shiraz
Province
Fars
Postal code

7376116678
Phone
+98 71 3233 2771
Email
ebrahimiv@sums.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
-
When the data will become available and for how long
-
To whom data/document is available
-
Under which criteria data/document could be used
-
From where data/document is obtainable
-
What processes are involved for a request to access data/document
-
Comments