Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Lactobacillus reuteri Supplementation versus Standard Triple Therapy for Helicobacter pylori Eradication among Patients with Dyspepsia

Protocol summary

Study aim

A comparison between standard triple therapy plus Lactobacillus reuteri supplementation versus standard triple therapy on H.pylori eradication among patients with dyspepsia

Design

This phase 2-3 randomized clinical trial will be done on 80 patients with dyspepsia .The patients will be randomly assigned into treatment groups using a computer-generated randomization table

Settings and conduct

Patients with dyspepsia will be randomly assigned into the intervention group and control group to receive treatment regimens for 10 days. Patients will be examined at the end of treatment to assess compliance rates and side effects of regimens and six weeks after that to assess H. Pylori eradication using stool antigen test. Data will be recorded on a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged between 18 to 70 years old with dyspepsia; H. Pylori documentation by antral biopsy (Rapid Urease Test or Giemsa staining) or Urea Breath Test; Exclusion criteria: Pregnancy or breast-feeding; Significant underlying diseases such as cardiac, pulmonary, renal, liver, endocrine, central nervous system (CNS) diseases and cancers; previous history of gastric surgery; History of taking triple therapy for H. Pylori eradication, proton pump inhibitor (PPI), histamine H2- receptor blocker (H2B) or antibiotic during previous two weeks, concomitant use of anticoagulant or corticosteroid

Intervention groups

Intervention group: Esomeperazole 40 mg BD + Amoxicillin 1000 mg BD + Clarithromycin 500 mg BD + Pyloshot BD,orally for 10 days Control group: Esomeperazole 40 mg BD + Amoxicillin 1000 mg BD + Clarithromycin 500 mg BD, orally for 10 days

Main outcome variables

H. Pylori eradication rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141201020178N10**
Registration date: **2020-09-11, 1399/06/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-11, 1399/06/21**
Update count: **0**

Registration date

2020-09-11, 1399/06/21

Registrant information

Name

Marjan Mokhtare

Name of organization / entity

Iran University of Medical sciences,Rasoul Akram Hospital,Colorectal Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-16, 1399/02/27

Expected recruitment end date

2020-10-17, 1399/07/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Lactobacillus reuteri Supplementation versus Standard Triple Therapy for Helicobacter pylori Eradication among Patients with Dyspepsia

Public title
Lactobacillus reuteri Supplementation for Helicobacter pylori Eradication among Patients with Dyspepsia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged between 18 to 70 years old with dyspepsia presentation H. Pylori documentation by antral biopsy (Rapid Urease Test or Giemsa staining) or Urea Breath Test

Exclusion criteria:
Pregnancy or breast- feeding Women taking oral contraceptive pill (OCP) Significant underlying diseases such as cardiac, pulmonary, renal, liver, endocrine, central nervous system (CNS) diseases and cancers Previous history of gastric surgery Patients taking triple therapy for H. Pylori eradication History of taking proton pump inhibitor (PPI), histamine H2- receptor blocker (H2B) or antibiotic during previous two weeks Concomitant use of anticoagulant or corticosteroid Previous history of taking monoamine oxidase (MAO) inhibitors or tricyclic antidepressants (TCA)

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is going to be carried out by block randomization, which works by randomizing participants within blocks such that an equal number is assigned to each group. Regarding this method, we will divide patients into two groups (male and female). Then we will provide six blocks which have a size of four, including: TCTC, TTCC, TCCT, ... (T: Treatment, C: Control), and we will assign the patients of each group into these blocks so that we will have equal treatment and control in each group (male and female).

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 Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, West Shahid Hemmat Highway, Intersection of Chamran and Sheikh Fazlollah Noori, Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2020-04-12, 1399/01/24

Ethics committee reference number
IR.IUMS.FMD.REC.1399.031

Health conditions studied

1

Description of health condition studied
Functional dyspepsia

ICD-10 code
K30

ICD-10 code description
Functional dyspepsia

2

Description of health condition studied
Helicobacter pylori

ICD-10 code
B96.81

ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Helicobacter Pylori eradication rate

Timepoint
Six weeks after the end of therapy

Method of measurement
Stool Antigen Test

Secondary outcomes

1

Description
Rate of supplementation's side effects
Timepoint
After end of the therapy
Method of measurement
Patients' follow-up checklist

2

Description
Patient's compliance rate
Timepoint
After end of the therapy
Method of measurement
Patients' follow-up checklist

Intervention groups

1

Description
Intervention group: Esomeperazole Cap 40 mg BD + Amoxicillin Cap 500 mg 2*BD + Clarithromycin Tab 500 mg BD + Pyloshot Tab for 10 days
Category
Treatment - Drugs

2

Description
Control group: Esomeperazole Cap 40 mg BD + Amoxicillin Cap 500 mg 2*BD + Clarithromycin Tab 500 mg BD for 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasul-e Akram hospital
Full name of responsible person
Dr. Marjan Mokhtare
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Sponsors / Funding sources

1

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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Marjan Mokhtare
Position
Associate professor of Gastroenterology and Hepatology
Latest degree
Subspecialist
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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
IPD collected for the primary outcome measure would be shared.
When the data will become available and for how long
It would be available 6 months after publication.
To whom data/document is available
This is only available for people working in academic institutions and/ or people working in businesses can also apply to receive it.
Under which criteria data/document could be used
People working in academic institutions
From where data/document is obtainable
Email address of corresponding author
What processes are involved for a request to access data/document
Up to three months after approval of ID documents
Comments