

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 21 6652 2845

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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

۱۴۳۹۶۱۴۵۳۵

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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Rasul-e Akram Hospital, Niayesh St., Sattarkhan Ave.,
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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

Other areas of specialty/work

Gastroenterology and Hepatology

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Person responsible for updating data

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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