Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparative Study of the Efficacy of Helicobacter pylori Eradication Therapy and Helicobcide in patients with Functional Dyspepsia: A Randomized Clinical Trial

Protocol summary

Study aim

Comparison of Helicobacter pylori treatment with four-drug regimen with helicobsid drug in people with indigestion.

Design

A clinical trial with a control group, double-blind, randomized, phase 3 on 112 patients, with randomization and random sequence construction, using a table of random numbers and through www.randomization.com.

Settings and conduct

Patients suffering from indigestion (without ulcers) with positive Helicobacter pylori infection will be included in the study in 1401 at the gastroenterology clinics affiliated to Mashhad University of Medical Sciences. Then randomly, one group of patients will be prescribed the four-drug regimen and the other group will be prescribed the drug Holcobsid once a day after lunch for one month. Demographic information, method of treatment, duration of treatment, response rate and result of stool exam ag before and after treatment will be recorded in the study checklist. Then the effectiveness of each of these two drug regimens will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria included Helicobacter pylori infection based on fecal antigen and not receiving four-drug treatment and not receiving antibiotics from the last two months until entering this study. Exclusion criteria included eradication of Helicobacter pylori and sensitivity to ginger.

Intervention groups

In the intervention group, helicobsid drug is prescribed to the patients in the form of oral capsules. In the control group, four standard drugs are prescribed.

Main outcome variables

Helicobacter pylori eradication

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231227060546N1**
Registration date: **2024-01-30, 1402/11/10**
Registration timing: **prospective**

Last update: **2024-01-30, 1402/11/10**
Update count: **0**

Registration date

2024-01-30, 1402/11/10

Registrant information

Name

Maryam Anvary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 3031

Email address

maryamanvary299@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative Study of the Efficacy of Helicobacter pylori Eradication Therapy and Helicobcide in patients with Functional Dyspepsia: A Randomized Clinical Trial

Public title
patients with Functional Dyspepsia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 45 years Consent to enter the study and take the prescribed drugs Patients with functional dyspepsia (without ulcers) The patient with Helicobacter pylori infection was Ag based on stool exam Not receiving four-drug treatment and not receiving antibiotics from the last two months until entering this study

Exclusion criteria:
Uncompensated heart failure Uncompensated liver failure Dialysis patients Patients with hematologic Malignancies Patients treated with anticonvulsants History of allergy to ginger pregnancy History of allergic disorders

Age
From **18 years** old to **45 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is block-based and the randomization unit is a block of four. The randomization tool and random sequence construction is done using the random number table and through the website www.randomization.com. In this study, we have two groups (indicated by the letters A and B).

Blinding (investigator's opinion)
Double blinded

Blinding description
Considering that this study will be designed in a double-blind manner, the patients, caregivers, and clinical evaluators are unaware of the contents of packages A and B. The drug and placebo will be produced in the faculty of pharmacology, and for proper blinding, the drug and the placebo will be completely similar in terms of color, size, and smell, and apart from the pharmacist, none of the participants and researchers will have access to them until the end of the study. They will not be aware.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Daneshgah Ave.

City
Mashhad

Province
Razavi Khorasan

Postal code
9138735499

Approval date
2023-05-30, 1402/03/09

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.248

Health conditions studied

1

Description of health condition studied
Dyspepsia (without ulcers) with positive Helicobacter pylori infection

ICD-10 code
K30

ICD-10 code description
Functional dyspepsia

Primary outcomes

1

Description
Eradication of Helicobacter pylori by antigen examination

Timepoint
A month afte3r completion of treatment

Method of measurement
Detection of Helicobacter pylori antigen in stool samples

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Taking Holcobside medicine (capsules containing 400 mg of ginger) once a day after lunch for one month

Category
Treatment - Drugs

2

Description
Control group: Treatment with four drugs including metronidazole, tetracycline, bismuth, a proton pump inhibitor such as pantoprazole, each once a day after lunch for a month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
GI clinic of Imam Reza Hospital
Full name of responsible person
Dr Maryam Anvary
Street address
Daneshgah Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Majid Ghayour Mobarhan
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Maryam Anvary
Position
Fellowship
Latest degree
Specialist
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