

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

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

#### Protocol summary

##### Study aim

Comparison of Helicobacter pylori treatment with four-drug regimen with helicobside 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](http://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 Helicobside 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, helicobside 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 Helicobicide 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 after completion of treatment

#### Method of measurement

Detection of Helicobacter pylori antigen in stool samples

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Taking Helicobicide 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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**Postal code**

9137913316

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**Email**

maryamanvary299@gmail.com

**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

**Street address**

Internal Medicine Ward, Emam Reza Hospital, Emam Reza Sq.

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Maryam Anvary

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**Latest degree**

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Mashhad

**Province**

Razavi Khorasan

**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