

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Survey of the effect of Helicobacter pylori eradication treatment on clinical symptoms improvement of patients with functional dyspepsia

Protocol summary

Summary

The purpose of this randomized, double blind trial is to determine the effect of Helicobacter pylori eradication treatment on clinical symptoms improvement of patients with functional dyspepsia. 300 hundred patients with functional dyspepsia are randomly assigned to receive Helicobacter pylori eradication treatment in addition to treatment of functional dyspepsia in intervention group or treatment of functional dyspepsia alone in control group for 2 weeks. Abdominal pain, bloating, and heartburn are measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008274017N4**
Registration date: **2010-09-13, 1389/06/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-09-13, 1389/06/22

Registrant information

Name

Hosseinali Habibinejad

Name of organization / entity

Islamic Azad University of Qom

Country

Iran (Islamic Republic of)

Phone

+98 21 7745 4051

Email address

ghadir@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2010-09-02, 1389/06/11

Expected recruitment end date

2011-03-14, 1389/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of the effect of Helicobacter pylori eradication treatment on clinical symptoms improvement of patients with functional dyspepsia

Public title

Effect of Helicobacter pylori eradication treatment on treatment of functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: complaining from dyspepsia, presence of functional dyspepsia, positive H.pylori test
Exclusion criteria: organic cause for dyspepsia

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Qom University of Medical Sciences

Street address

Saheli Ave

City

Qom

Postal code**Approval date**

empty

Ethics committee reference number

263/3

Health conditions studied**1****Description of health condition studied**

Functional dyspepsia

ICD-10 code

F45.3

ICD-10 code description

somatoform autonomic dysfunction

Primary outcomes**1****Description**

abdominal pain

Timepoint

before treatment, 2 weeks after treatment, 1 month after treatment

Method of measurement

visual analog scale

2**Description**

bloating

Timepoint

before treatment, 2 weeks after treatment, 1 month after treatment

Method of measurement

visual analog scale

3**Description**

heartburn

Timepoint

before treatment, 2 weeks after treatment, 1 month after treatment

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups**1****Description**

pantoprazole, tablet 20 mg, twice daily for 1 month- amoxicillin, capsule 500 mg, 2 capsules twice daily for 2 weeks - clarithromycin, tablet 500 mg, 2 tablets twice daily for 2 weeks

Category

Treatment - Drugs

2**Description**

Pantoprazole, tablet 20 mg, twice daily for 1 month

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr. Mohammadreza Ghadir Office

Full name of responsible person**Street address****City**

Qom

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qom University of Medical Sciences

Full name of responsible person

Miri

Street address

Qom University of Medical Sciences, Saheli Ave

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Qom

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qom University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Qom University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Ghadir

Position

Gastroenterologist

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty