Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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/د

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
City
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

Other areas of specialty/work

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Other areas of specialty/work

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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