

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial comparing of the effect of *Helicobacter pylori* eradication and its non-eradication on functional dyspepsia in patients referring to the Gastroenterology Clinic of Birjand in 2015 and 2016

Protocol summary

Study aim

To determine the effect of *Helicobacter pylori* eradication on functional dyspepsia in patients

Design

In this randomized clinical trial, 117 eligible patients were incorporated using convenience sampling method and assigned into one of the two study groups using table of random numbers. From among them, 100 patients completed the study.

Settings and conduct

The study was carried out in the Gastroenterology Clinic of Birjand in 2015 and 2016. At first, all patients underwent endoscopy to reject organic causes and gastric sampling to confirm infection. Participants were randomly assigned into two groups using the table of random numbers. The intervention group was treated with quadruple therapy for *Helicobacter pylori* eradication and the control group was treated with anti-acid. and the complications and response rate to treatment were assessed in two groups.

Participants/Inclusion and exclusion criteria

Patients with functional dyspepsia who present abdominal perineal, heartburn, nausea, vomiting, or upper abdominal pain, and some patients with early fullness; absence of organ diseases such as gastroesophagitis, ulcer, and gastric and endometrial cancers according to endoscopy; no history of gastric surgery; no history of eradicating *Helicobacter pylori*; positive results for *Helicobacter pylori* infection according to endoscopy. Exclusion criteria: Patients who fail to complete treatment; intolerance for anti-*Helicobacter pylori* antibiotics; withdrawal from the study for any reason.

Intervention groups

The controls received omeprazole 40 mg twice daily for four weeks. For two weeks, the cases received clarithromycin 500 mg twice daily, amoxicillin 1 g twice

daily, and bismuth 262 mg twice daily. They also received omeprazole 40 mg twice daily for four weeks. After the intervention was finished, urease breathing test was performed to assess eradication, and the complications of eradication and the response to treatment were evaluated in each group.

Main outcome variables

Response to treatment; Complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017756N37**

Registration date: **2018-02-06, 1396/11/17**

Registration timing: **retrospective**

Last update: **2018-02-06, 1396/11/17**

Update count: **0**

Registration date

2018-02-06, 1396/11/17

Registrant information

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Name of organization / entity

Birjand University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-13, 1394/12/23

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

2015-03-21, 1394/01/01

Actual recruitment end date

2017-03-19, 1395/12/29

Trial completion date

empty

Scientific title

A clinical trial comparing of the effect of Helicobacter pylori eradication and its non-eradication on functional dyspepsia in patients referring to the Gastroenterology Clinic of Birjand in 2015 and 2016

Public title

Effect of Helicobacter pylori eradication on functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with functional dyspepsia who present abdominal perineal, heartburn, nausea, vomiting, or upper abdominal pain, and some patients with early fullness absence of organ diseases such as gastroesophagitis, ulcer, and gastric and endometrial cancers according to endoscopy no history of gastric surgery no history of eradicating Helicobacter pylori positive results for Helicobacter pylori infection according to endoscopy

Exclusion criteria:

Patients who fail to complete treatment Intolerance for anti-Helicobacter pylori antibiotics Withdrawal from the study for any reason

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **117**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were allocated into study groups via simple randomization method.

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 Birjand University of Medical Sciences

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Ghaffari St.

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Birjand

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South Khorasan

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9717853577

Approval date

2016-03-12, 1394/12/22

Ethics committee reference number

IR.BUMS.REC.1394.359

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

functional dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

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

Eradication of Helicobacter pylori

Timepoint

At the end of the intervention

Method of measurement

Urease breathing test

2**Description**

Response to treatment

Timepoint

Before and after intervention

Method of measurement

Endoscopy

Secondary outcomes**1****Description**

Dry mouth

Timepoint

After intervention is finished

Method of measurement

Physical examination and questioning the patient

2

Description

nausea and vomiting

Timepoint

After intervention is finished

Method of measurement

Physical examination and questioning the patient

3

Description

Bitter mouth

Timepoint

After intervention is finished

Method of measurement

Physical examination and questioning the patient

4

Description

Stomachache

Timepoint

After intervention is finished

Method of measurement

Physical examination and questioning the patient

5

Description

Diarrhea

Timepoint

After intervention is finished

Method of measurement

Questioning the patient

6

Description

Skin rash

Timepoint

After intervention is finished

Method of measurement

Physical examination and questioning the patient

7

Description

Severe headache

Timepoint

After intervention is finished

Method of measurement

Physical examination and questioning the patient

Intervention groups

1

Description

Intervention Group (quadruple therapy): For two weeks, the cases received clarithromycin 500 mg twice daily, amoxicillin 1 gram twice daily, and bismuth 262 mg twice daily. They also received omeprazole 40 mg twice daily for four weeks.

Category

Treatment - Drugs

2

Description

Control Group (omeprazole): The controls received omeprazole 40 mg twice daily for four weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Tahmine Tavakoli's Office

Full name of responsible person

Farzane Dashti

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Birjand 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
Birjand University of Medical Sciences
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Medical Doctor
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
Not applicable
Title and more details about the data/document
Study Protocol
When the data will become available and for how long
The study protocol will be available to readers in the extracted paper.
To whom data/document is available
all the readers of the paper
Under which criteria data/document could be used

No limitation
From where data/document is obtainable
the journal that publishes the paper
What processes are involved for a request to access

data/document
guidelines of the journal
Comments