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

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5680

Email address

mbroozgar@bums.ac.ir

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
Street address
Ghaffari St.
City
Birjand
Province
South Khorasan
Postal code
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 intevention
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
ntervention 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
Street address
Ghaffari St.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3244 6895
Email
naz.parisa@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr Tooba Kazemi
Street address
Ghaffari St.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3238 1200
Email
Drtoobakazemi@gmail.com

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
Full name of responsible person
Farzaneh Dashti
Position
Medical Doctor
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Ghaffari St.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3244 6895
Email
naz.parisa@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Farzaneh Dashti
Position
Medical Doctor
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Ghaffari St.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3244 6895
Email
naz.parisa@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohammad Bagher Roozgar
Position
Translator
Latest degree
Master
Other areas of specialty/work
Others
Street address
Ghaffari St.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5680
Email
hadirooz@gmail.com

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