Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative study of the effect of levofloxacin with metronidazole in the 4-drug eradication regimen of Helicobacter pylori

Protocol summary

Study aim
Investigating the local antibiotic resistance of Helicobacter pylori to provide physicians with more informed drug choices for better treatment of Helicobacter infection.

Design
Clinical trial with parallel groups, randomized to two treatment groups (Random allocation), phase 2 on 334 patients.

Settings and conduct
At first, a written personal consent will be obtained from all patients referring to Mufteh Yasouj clinic. Patients will be between 15 and 80 years old. Confirmation of H. pylori diagnosis in all the people investigated in this study will be done by stool antigen test. Patients who are confirmed to have H. pylori diagnosis will be randomly and automatically in one of the two treatment groups of four eradication drugs. H pylori based on levofloxacin (group A) or metronidazole (group B) will be 1.1. Blinding was not done.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Patients with peptic ulcer 2. Mallet's lymphoma 3. Atrophic gastritis 4. Intestinal metaplasia 5. First degree people with stomach cancer 6. Treatment-resistant dyspepsia Exclusion criteria : 1. Previous history of H pylori treatment 2. History of gastrectomy 3. Having gastric cancer 4. Pregnant women 5. Use of antibiotics in the last one month, PPI or h2blocker use in the last two weeks 6. Chronic liver, kidney or lung disease.

Intervention groups
The intervention group includes patients with dyspepsia who are indicated for Helicobacter pylori treatment and receive intervention A. The comparison group includes patients with dyspepsia who are indicated for Helicobacter pylori treatment and receive intervention B.

Main outcome variables
Investigating the local antibiotic resistance of Helicobacter pylori; More informed drug choices for doctors to better treat Helicobacter infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240803062624N1**
Registration date: **2024-10-03, 1403/07/12**
Registration timing: **retrospective**

Last update: **2024-10-03, 1403/07/12**
Update count: **0**

Registration date
2024-10-03, 1403/07/12

Registrant information

Name
Ladan Delgarm

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3230 8515

Email address
ladan.delgarm@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2024-01-30, 1402/11/10

Actual recruitment start date
2023-09-03, 1402/06/12

Actual recruitment end date
2024-03-05, 1402/12/15

Trial completion date
empty

Scientific title

Comparative study of the effect of levofloxacin with metronidazole in the 4-drug eradication regimen of Helicobacter pylori

Public title
"Effect of metronidazol in treatment of hpylori""Effect of levofloxacin in treatment of hpylori"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to Shahid Muftah Yasouj clinic with symptoms of dyspepsia, whose H. pylori infection was confirmed by stole antigen test and indicated for H. pylori eradication Patients with peptic ulcer Malt lymphoma Atrophic gastritis Intestinal metaplasia First degree people with stomach cancer Treatment-resistant dyspepsia
Exclusion criteria:
Previous history of H pylori treatment History of gastrectomy Having gastric cancer Pregnant women Use of antibiotics in the last one month, use of ppi or h2blocker in the last two weeks Chronic liver, kidney or lung disease
Age
From **15 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **334**
Actual sample size reached: **321**
Randomization (investigator's opinion)
Randomized
Randomization description
First, we put the number of participants (167 A cards and 167 B cards) in a dark box, then the selection is made by randomly drawing a card from the box.
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 Yasuj University of Medical Sciences
Street address
Yasuj, Shahid Motahari Blvd., Yasouj University of Medical Sciences, Yasouj
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Approval date
2023-10-11, 1402/07/19
Ethics committee reference number
IR.YUMS.REC.1402.115

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection
ICD-10 code
B96.81
ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Helicobacter pylori stool antigen
Timepoint
First study and 4 weeks after treatment
Method of measurement
Helicobacter pylori stool antigen test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: In this group, omeprazole 20 mg twice a day (bid) for two weeks along with an antibiotic regimen (amoxicillin 1 gram twice a day (56 tablets during the treatment period) and two bismuth citrate tablets twice daily and levofloxacin 500 mg daily) and then continue to take omeprazole for 6 weeks without antibiotics and alone, and after this 6-week period, the patient 4 weeks later without taking drugs and antibiotics for the root test Kenny refers to the stool antigen test method.The drugs used in the study are from the pharmaceutical companies of Farabi and Obeidi.
Category
Treatment - Drugs

2

Description
Intervention group B: In this group, omeprazole 20 mg twice a day along with antibiotic regimen (amoxicillin 1 gram twice a day and two bismuth citrate tablets twice a day and metronidazole 500 mg twice a day) were given for two weeks. and then continue taking omeprazole for 6 weeks without antibiotics and alone, and after this 6-week period, the patient will refer to stole antigen test method 4 weeks later without taking drugs and antibiotics.The drugs used in the study are from the pharmaceutical companies of Farabi and Obeidi.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mofateh clinic

Full name of responsible person
Bahram Mohammadi

Street address
Golestan Alley 15 ,Pasdaran St.

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Yasuj

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Kohgilouyeh-va-Boyrahmad

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7135646196

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Amin Hosseini

Street address
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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
Yasouj 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
Yasouj University of Medical Sciences

Full name of responsible person
Ladan Delgarm

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
No. 2 , 6th Alley , Khayyam St ., Shiraz City

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Fars

Postal code
7135646196

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Ladan.delgarm@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Ladan Delgarm

Position
Resident

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Person responsible for updating data

Contact

Name of organization / entity

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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

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