Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of OABM WITH OABF regimens in In the treatment of Helicobacter pylori patients

Protocol summary

Study aim

: Comparison of the effect of OABM WITH OABF regimens in In the treatment of Helicobacter pylori patients referred to Mofateh Clinic1 of Yasuj University of Medical Sciences in 2022-2023

Design

Phase 3 clinical trial in two parallel groups receiving the regimen ABF(omeprazolo_furazolidone_bismuth subcitrate_ amoxicillin) and OABM(omeprazolo_metronidazole_bismuth subcitrate _amoxicillin), single blind, randomized using a table of numbers

Settings and conduct

This study will be conducted in the field of Helicobacter pylori infection treatment in Yasouj University of Medical Sciences in Fatah 1 Clinic. The study is performed on patients with personal consent. Patients will receive ABF or OABM drug in two groups randomly. The researchers were blinded to the type of intervention assigned to the patients.

Participants/Inclusion and exclusion criteria

Patients with dyspepsia, without indication for endoscopy, with a positive Helicobacter diagnostic test, including Helicobacter stool antigen test

Intervention groups

In one group, omeprazole 20 mg twice a day (Bid) is continued for two weeks with antibiotics and then for 6 weeks without antibiotics, and after 4 weeks of this treatment period, the patient gives a stool antigen test to check the eradication of Helicobacter pylori. Amoxicillin 1 gram twice a day, bismuth citrate tablets twice a day and furazolidone 200 mg twice a day (Bid), in the other group omeprazole 20 mg twice a day along with antibiotics for 2 weeks and then for 6 weeks without antibiotics and alone and after this 6-week period, the patient will refer to stool antigen test method 4 weeks later without taking drugs and antibiotics for eradication test. In this group, amoxicillin one gram twice in day and two tablets of bismuth citrate twice a day (4 tablets a day) and metronidazole 500 mg twice a day

Main outcome variables

Helicobacter pylori antigen negativity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150622022869N11**
Registration date: **2023-06-11, 1402/03/21**
Registration timing: **prospective**

Last update: **2023-06-11, 1402/03/21**
Update count: **0**

Registration date

2023-06-11, 1402/03/21

Registrant information

Name

Moslem Sedaghattalab

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 0163

Email address

m.sedaghattalab@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2023-07-01, 1402/04/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of OABM WITH OABF regimens in In the treatment of Helicobacter pylori patients

Public title
Comparison of the effect of OABM WITH OABF regimens in In the treatment of Helicobacter pylori patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A patient who underwent endoscopy and has peptic ulcer disease (PUD). Patients with dyspepsia without endoscopic indication have a positive Helicobacter diagnostic test, including Helicobacter stool antigen test and.... Patients with maltoma Endoscopy patients with nud (non-ulcer dyspepsia) and patients with a history of cancer in their first degree relatives will be included in the study. Patients who have a history of pud and are Helicobacter positive and are taking NSAID Treatment-resistant dyspepsia Patient satisfaction
Exclusion criteria:
Previous history of H pylori treatment Allergy to antibiotics Allergy to PPI History of gastrectomy Having gastric cancer pregnant women Taking antibiotics in the last month Taking PPI or h2blocker in the last two weeks Chronic liver, kidney or lung disease History of Fauvism
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Random number table method is used for randomization in this study. In this method, random table is used for randomization and patients are assigned random numbers from the table. Patients in each of the two study groups will be assigned to one of the two groups based on random numbers.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study will be single blind, in which the researchers of this study will be blinded to the type of intervention assigned to the patients.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee ofYasuj University of Medical Sciences
Street address
Dr. Jalil St., campus of Yasouj University of Medical Sciences., Yasuj., Iran
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591994799
Approval date
2023-01-03, 1401/10/13
Ethics committee reference number
IR.YUMS.REC.1401.159

Health conditions studied

1

Description of health condition studied
helicobacter pylori (h. 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
Frequency distribution of Helicobacter pylori antigen negativity
Timepoint
12weeks after the start of the study
Method of measurement
Stool antigen test

2

Description
Drug side effects
Timepoint
12 weeks
Method of measurement

Clinical examination and patient presentation

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: omeprazole 20 mg twice a day (Bid) is continued for two weeks with antibiotics and then for 6 weeks without antibiotics, and after 4 weeks of this treatment period, the patient gives a stool antigen test to check the eradication of Helicobacter pylori. Amoxicillin 1 gram twice a day, bismuth citrate tablets twice a day and furazolidone 200 mg twice a day (Bid)

Category

Treatment - Drugs

2

Description

Second intervention group: omeprazole 20 mg twice a day along with antibiotics for 2 weeks and then for 6 weeks without antibiotics and alone and after this 6-week period, the patient will refer to stool antigen test method 4 weeks later without taking drugs and antibiotics for eradication test. In this group, amoxicillin one gram twice in day and two tablets of bismuth citrate twice a day (4 tablets a day) and metronidazole 500 mg twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Muftah Clinic

Full name of responsible person

Moslem Sedaghattalab

Street address

Dr. Jalil St., campus of Yasouj University of Medical Sciences., Yasuj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hossaini Motlagh

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aminhomo@yahoo.com

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

Moslem Sedaghttalab

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Dr. Jalil St., campus of Yasouj University of Medical Sciences,. Yasuj

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
The data of this study can be shared without mentioning individuals and in aggregate form after the publication of the article through administrative correspondence.
When the data will become available and for how long
After printing the article
To whom data/document is available
this is available for people working in academic institutions or people working in businesses can also apply to receive it.
Under which criteria data/document could be used
Any analysis on the data will be allowed
From where data/document is obtainable
m.sedaghattalab@yuma.ac.com
What processes are involved for a request to access data/document
After sending the email, the required data will be available for up to 1 month
Comments