

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of Therapeutic Effects of Metronidazole in Variable Doses in Eradication of Helicobacter pylori in Dyspeptic Patients

Protocol summary

Study aim

Comparison of the Efficacy of Drug Regimen with High Dose and Standard Dose of Metronidazole on Helicobacter pylori Eradication

Design

In this Randomized, Single Blinded Parallel Group Clinical Trial Study, 170 Patients with Positive Helicobacter Pylori Stool Antigen Test are Randomly Divided into two Groups of 85 Patients and each Group are Treated with One of the A or B regimen with Variable Dose of Metronidazole for 14 Days.

Settings and conduct

170 Patients with Complaint of Dyspepsia and Positive Helicobacter pylori Stool antigen Test who will Refer to Tadbir's Polyclinic of Urmia, are Divided into Group A and B, by Simple Randomization Method by Using Random Allocation Software. each Group will Consist of 85 Patients. These Groups will Receive Quadruple Therapy Regimen for 2 weeks. For group A Standard dose of Metronidazole and for Group B High Dose Metronidazole will be Given. Then, 4 Weeks after the Termination of Treatment, Drugs Adverse Effects will be Asked and Helicobacter pylori Eradication will be Assessed by Stool Antigen Test.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Dyspeptic Patients Older than 18 Years who Have Positive Helicobacter pylori Stool Antigen Test. Exclusion Criteria: Patients who Do not Refer after Receiving the Medications, Patients who Take the Medications for less than 10 Days, Pregnant or Breastfeeding Women, Patients with the History of Major Cardiac, Pulmonary, Renal or Hepatic Disease, History of Known Side Effects to the Medications of Therapeutic Regimen

Intervention groups

Groups A and B will Receive Quadruple Therapy Regimen for 14 Days composed of Omeprazole 20 mg, Bismuth Subcitrate 135 mg, Amoxicillin 1000mg (All Given BID) with Metronidazole 500mg BID in Group A and TDS in

Group B.

Main outcome variables

Success Rate in Eradicating of Helicobacter pylori Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211012052740N1**

Registration date: **2021-10-16, 1400/07/24**

Registration timing: **prospective**

Last update: **2021-10-16, 1400/07/24**

Update count: **0**

Registration date

2021-10-16, 1400/07/24

Registrant information

Name

Hadi Mirabasvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3660 7369

Email address

abasvandh08@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Therapeutic Effects of Metronidazole in Variable Doses in Eradication of Helicobacterpylori in Dyspeptic Patients

Public title

Effect of Variable Doses of Metronidazole in Treatment of Helicobacterpylori

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Dyspeptic Patients with Positive Helicobacterpylori Stool Antigen Test Older than 18 Years Old Persons

Exclusion criteria:

No Referring After Taking the Medication Taking Medications for Less than 10 Days Pregnant or Breastfeeding Women Patients with the History of Major Cardiac, Pulmonary, Renal or Hepatic Disease History of Known Side Effects to the Medications of Therapeutic Regimen Taking Antibiotic during the Last Month

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is Done in Simple Method And Patients are Divided into Control and Intervention Groups in a List of Codes Prepared by Random Allocation Software.The Subjects are Assigned into Different Groups by Random Allocation. Allocation Concealment is Obtained by Maintaining the Randomization List by Study Statistician.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients Participating in the Study are not be Informed about the Type of their Treatment Regimen

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

Urijans Alley, resalat Ave., Urmia University of Medical Sciences

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2021-08-15, 1400/05/24

Ethics committee reference number

IR.UMSU.REC.1400.175

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**

Eradication of Helicobacter pylori Infection

Timepoint

Four Weeks after the Termination of Treatment

Method of measurement

Helicobacter pylori Stool Antigen Test

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

Drug Adverse Effects Including: Nausea, Abdominal Pain, Metallic Taste, Diarrhea

Timepoint

Four Weeks after Starting the Treatment

Method of measurement

Questionnaire

2**Description**

The Tolerance to Accepting the Treatment (Taking

Medications more than 10 Days)
Timepoint
Two Weeks after Starting the Treatment
Method of measurement
Questionnaire

Intervention groups

- 1
Description
Intervention group: Group B Receives Following Medications for 14 Days: Tab Metronidazole 500 mg TDS, Omeprazole 20 mg BID, Amoxicillin 1000 mg BID, Bismuth Subcitrate 135 mg BID
Category
Treatment - Drugs
- 2
Description
Control group: Group A Receives Following Medications for 14 Days: Tab Metronidazole 500 mg BID, Omeprazole 20 mg BID, Amoxicillin 1000 mg BID, Bismuth Subcitrate 135 mg BID
Category
Treatment - Drugs
- Recruitment centers**
- 1
Recruitment center
Name of recruitment center
Tadbir's Polyclinic
Full name of responsible person
mohammadreza mohammad hoseiny azar
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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

Recruitment centers

- Person responsible for general inquiries**
- Contact**
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Mohammadreza Mohammad Hoseiny Azar
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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- Sponsors / Funding sources**
- 1
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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

Person responsible for updating data**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Mohammadreza Mohammad Hoseiny Azar

Position

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Other areas of specialty/work

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