

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The Efficacy of Metronidazole , Amoxicilin, Bismuth, Omeprazole - (OMAB) Based Quadruple Therapy for Eradication of Helicobacter Pylori Infection in Hamedanian Patients

Protocol summary

Summary

Helicobacter pylori has strong association with peptic ulcer in patients with peptic ulcer. It is recommended to eradicate the germ. Various treatment regimes exist with different efficacy and side effects. Choosing treatment regime depends on effectiveness, tolerance, resistance to antibiotics and drug price. The aim of treatment is eradication of infection in 85-90% of cases. Resistance to antibiotic is the most common cause of failure in treatment in patients with full participation. Occurrence rate and resistant species to antibiotics is different in various parts of the world. The most effective treatment regime in Iranian's literature is herbal medications based on claritromycine or furazolidon but because of side effects of Furazolidon and high cost of claritromycine, most physicians prescribe Metronidazole, Amoxi ciline, Bismout and Omeprazol (OMAB regime). Due to drug resistance in different parts, this study is necessary to determine effectiveness of drug regime. Patients referring to Shahid Beheshti hospital of Hamadan with peptic ulcer symptoms undergo Endoscopy. In the case of any lesion due to Helicobacter, sample was taken by biopsy and after confirming germ by pathologist, patients treated whit four drugs including 2omg omeprazol , 1000mg Amoxiciline, 240mg Bismute and 500mg Metronidazole twice daily for two weeks. Then they treated with omeprazole for 4 weeks. After 3 months of treatment urea Breath test (UBT) will be done by labeled carbon. If the test was negative, eradication is successful. Obtained samples in 1 year will be reported and results will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901213676N1**

Registration date: **2010-05-11, 1389/02/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-05-11, 1389/02/21

Registrant information

Name

Mohammad Reza Tavakoli

Name of organization / entity

Hamedan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research committee of Hamedan University of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Metronidazole , Amoxicilin, Bismuth,

Omeprazole – (OMAB) Based Quadruple Therapy for Eradication of Helicobacter Pylori Infection in Hamedanian Patients	
Public title	The Efficacy of Metronidazole , Amoxicilin, Bismuth, Omeprazole – (OMAB) Based Quadruple Therapy for Eradication of Helicobacter Pylori Infection in Hamedanian Patients
Purpose	Treatment
Inclusion/Exclusion criteria	All patients with peptic ulcer symptoms who need Endoscopy based on history an physical exam entered into this study. Exclusion criteria: antibiotic consumption in recent month; proton pump inhibitory drug or Bismut in recent 2 weeks or bleeding or any contradiction to endoscopy. In case of existing tumour in Endoscopy and not completing treatment, patients were also excluded
Age	No age limit
Gender	Both
Phase	2
Groups that have been masked	No information
Sample size	Target sample size: 100
Randomization (investigator's opinion)	N/A
Randomization description	
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Single
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Hamedan university of medical sciences
Street address	Mahdieh street
City	Hamedan
Postal code	00986517838736
Approval date	2010-02-25, 1388/12/06
Ethics committee reference number	175857/9/35/16/11-10-8-6-5-3-1 -پ

Health conditions studied	
<u>1</u>	
Description of health condition studied	Peptic ulcer disease
ICD-10 code	K27.9, K26
ICD-10 code description	Peptic ulcer, Deudenal ulcer, Gastritis
Primary outcomes	
<u>1</u>	
Description	Helicobacter pylori infection
Timepoint	6 weeks after treatment
Method of measurement	Urea breathing test
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	OMAB Regime, Omeprazole20mg- metronidazole 500mg- amoxicillin1000mg-bismuth240mg twice daily for2weeks then omeprazole20mg for 4weeks
Category	Treatment - Drugs
Recruitment centers	
<u>1</u>	
Recruitment center	
Name of recruitment center	SHAHID BEHESHTI HOSPITAL
Full name of responsible person	Dr Mohammad Reza Tavakoli
Street address	ERAM STREET
City	HAMEDAN
Sponsors / Funding sources	
<u>1</u>	
Sponsor	
Name of organization / entity	Hamedan university of medical sciences
Full name of responsible person	Dr Ali Reza Khalilian
Street address	

Mahdieh street
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty