

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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 furazoulidon but because of side effects of Furazoulidon 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 with four drugs including 20mg 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**  
Iran (Islamic Republic of)  
**Phone**  
+98 81 1838 6295  
**Email address**  
mr.tavakoli@umsha.ac.ir

##### 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

#### 1

##### 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

#### 1

##### 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

#### 1

##### Description

Helicobacter pylori infection

##### Timepoint

6 weeks after treatment

##### Method of measurement

Urea breathing test

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

OMAB Regime, Omeprazole20mg- metronidazole 500mg- amoxicillin1000mg-bismuth240mg twice daily for 2 weeks then omeprazole20mg for 4 weeks

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### 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

#### 1

##### 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**  
Hamedan university of medical sciences  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*