

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of three-drug regimen against H. pylori infection versus four-drug regimen in patients with dyspepsia or peptic ulcer disease: a randomized clinical trial

#### Protocol summary

##### Summary

Objectives: To assess the effect of three-drug regimen against H. pylori infection versus four-drug regimen in patients with dyspepsia or peptic ulcer disease. Design: a randomized clinical trial. Setting and conduct: The eligible patients with dyspepsia or peptic ulcer disease who will refer to Shahid Behashti Hospital during the study period will be enrolled into the trial. Inclusion criteria: dyspepsia for at least 3 months; H. pylori infection, age of 18 to 70 years. Exclusion criteria: pregnancy or breastfeeding; history of surgery of upper stomach or bowel; gastric cancer; renal or liver failure. Intervention group 1: Capsule Omeprazole 20 mg twice a day and capsule Amoxicillin 1000 mg twice a day and capsule clarithromycin 500 mg twice a day for 14 days. Intervention group 2: Capsule Omeprazole 20 mg twice a day and capsule Amoxicillin 1000 mg twice a day and capsule Levofloxacin 500 mg twice a day for 14 days. Control group: Capsule Omeprazole 20 mg twice a day and capsule Amoxicillin 1000 mg twice a day and tablet Metronidazole 500 mg twice a day and tablet Bismuth 240 mg twice a day for 14 days. Primary outcome: Assessing the irradiation of H. pylori infection 4 to 6 weeks after treatment using urease respiratory test with labeled carbon. Secondary outcome: Nothing. Randomization: The patients will be randomly assigned to intervention and control groups using random number table. Blinding: Not blinded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201605189014N100**  
Registration date: **2016-06-08, 1395/03/19**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-06-08, 1395/03/19

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellor for Research the Technology, Hamadan  
University of Medical Sciences

##### Expected recruitment start date

2016-06-04, 1395/03/15

##### Expected recruitment end date

2017-06-05, 1396/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of three-drug regimen against H. pylori infection versus four-drug regimen in patients with dyspepsia or peptic ulcer disease: a randomized clinical trial

## Public title

Effect of three-drug regimen against H. pylori infection versus four-drug regimen in patients with dyspepsia or peptic ulcer disease

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: dyspepsia for at least 3 months; H. pylori infection, age of 18 to 70 years. Exclusion criteria: pregnancy or breastfeeding; history of surgery of upper stomach or bowel; gastric cancer; renal or liver failure.

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **150**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using random number table. Blinding: Not blinded.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

##### Postal code

6517838695

#### Approval date

2016-01-23, 1394/11/03

#### Ethics committee reference number

IR.UMSHA.REC.1394.445

## Health conditions studied

### 1

#### Description of health condition studied

Dyspepsia

#### ICD-10 code

K30

#### ICD-10 code description

Dyspepsia

## Primary outcomes

### 1

#### Description

Assessing the irradiation of H. pylori infection

#### Timepoint

4 to 6 weeks after treatment

#### Method of measurement

using urease respiratory test with labeled carbon

## Secondary outcomes

### 1

#### Description

Nothing

#### Timepoint

Nothing

#### Method of measurement

Nothing

## Intervention groups

### 1

#### Description

Intervention group 1: Capsule Omeprazole 20 mg twice a day and capsule Amoxicillin 1000 mg twice a day and capsule clarithromycin 500 mg twice a day for 14 days.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Capsule Omeprazole 20 mg twice a day and capsule Amoxicillin 1000 mg twice a day and capsule Levofloxacin 500 mg twice a day for 14 days.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: Capsule Omeprazole 20 mg twice a day and capsule Amoxicillin 1000 mg twice a day and tablet Metronidazole 500 mg twice a day and tablet Bismuth 240 mg twice a day for 14 days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid Beheshti Hospital

**Full name of responsible person**

Dr Anvar Bahrami

**Street address**

Shahid Beheshti Hospital, Eram Ave.

**City**

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor for Research the Technology, Hamadan  
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**

Shahid Beheshti Hospital

**Full name of responsible person**

Dr Anvar Bahrami

**Position**

Internal Medicine Resident

**Other areas of specialty/work****Street address**

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med5921@gmail.com

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti Hospital

**Full name of responsible person**

Dr Maryam Hasan Zarini

**Position**

Internist

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

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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*