Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of three-drug regimen against H. pylori infection versus four-drug regiment 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 regiment 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 lever 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 for14 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

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Name of organization / entity
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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 regiment 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 regiment 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 lever 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 for14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr Anvar Bahrami
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Shahid Beheshti Hospital, Eram Ave.
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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
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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
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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