Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of standard triple drugs therapy and sequential regimen for Helicobacter- pylori eradication

Protocol summary

Summary

This study is a randomized controlled clinical trial, performed in the patients suffering from dyspepsia, in whom Helicobacter pylori infection was detected by endoscopic method, serology, and urease breathe test with C14. These 140 patients were randomly divided into equal groups. The patients in the first group (control) were treated by omeprazole capsule 20 mg BID, Amoxicillin capsule 1 gr BID, clarithromycin tablet 500mg BID for 14 days; while the patients in the second group were treated by omeprazole capsule 20 mg for 14 days, Amoxicillin capsule 1 gr BID for 5 days, then clarithromycin tablet 500 mg and Tinidazole tablet 500 mg BID for other 5 days. 4-6 weeks after the treatment, we compared the eradication of H.pylori between groups by urease breathe test with C14 and evaluated the effectiveness of the treatment regimen in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104226030N5**
Registration date: **2011-07-08, 1390/04/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-08, 1390/04/17

Registrant information

Name

Bahram Garmrudi nejhad rostamy

Name of organization / entity

Hamedan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0704

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Recruitment status

Recruitment complete

Funding source

Vice- chancellor for research of Hamedan university of medical sciences

Expected recruitment start date

2011-02-20, 1389/12/01

Expected recruitment end date

2011-08-23, 1390/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of standard triple drugs therapy and sequential regimen for Helicobacter- pylori eradication

Public title

Comparison of standard triple drugs therapy and sequential regimen for Helicobacter- pylori eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : patients in whom Helicobacter pylori infection was detected by endoscopic method, serology, and urease breathe test with C14. Exclusion criteria: past history of Helicobacter pylori infection treatment , upper gastero- intestinal surgery, Gasteric cancer, renal or liver failure, breast feeding & pregnant woman.

Age

No age limit

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice- chancellor for research of Hamadan university of medical sciences
Street address
Shahid fahmide blv,Hamadan university of medical sciences ,Vice- chancellor for research,
City
Hamadan
Postal code
65178/518
Approval date
2011-02-08, 1389/11/19
Ethics committee reference number
پ/172866/9/35/16

Health conditions studied

1

Description of health condition studied
Dyspepsia
ICD-10 code
K30
ICD-10 code description
Dyspepsia

Primary outcomes

1

Description
Eradication of Helicobacter pylori
Timepoint
4-6 weeks after treatment
Method of measurement
Rate of eradication by Urease breathe test with C14

Secondary outcomes

empty

Intervention groups

1

Description
Patients in the second group (intervention) were treated by omeprazole capsule 20 mg for 14 days, Amoxicillin capsule 1 gr BD for 5 days, then clarithromycin tablet 500 mg and Tinidazole tablet 500 mg BD for other 5 days
Category
Treatment - Drugs

2

Description
The patients in the first group (control) were treated by triple standard therapy (omeprazole capsule 20 mg BID, Amoxicillin capsule 1 gr BID, clarithromycin tablet 500mg BID for 14 days)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid beheshty hospital & private service
Full name of responsible person
Dr Bahram Garmrudi nejhad rostami
Street address
Shahid beheshty hospital, Eeram blvd
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research of Hamadan university of medical sciences
Full name of responsible person
Dr Ali Ghaleiiha
Street address
Shahid Fahmide blvd
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 of 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
Hamadan university of medical sciences

Full name of responsible person
Dr Bahram Garmrudi Nejhad Rostami

Position
Resident of internal medicine

Other areas of specialty/work

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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