Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing sequential treatment with classic triple therapy for helicobacter pylori eradication

Protocol summary

Summary

The primary aim of this study is to compare eradication rate and the acceptability of a new sequential treatment regimen. We designed an open-label, randomized, parallel-arm study and 130 patients with persistent dyspepsia, who refereed for upper endoscopy and their rapid urease test is positive, are recruited for helicobacter pylori eradication. Patients with history of HP eradication or on PPI or recent antibiotic therapy are excluded. Patients are randomized into two groups: sequential and classic triple therapy. Triple therapy group are prescribed omeperazol 20mg BID and amoxcycilin 1000mg /12h and chlarythrimicin 500mg/12h for 10 days. Sequential treatment group are prescribed amoxcycilin 1000mg/12h and omeprazol 20mg/bid for first 5 days and chlarythromicin 500mg/12h and omeprazol 20mg/BID and metronidazol 500mg/12h for next 5 days. Both groups will have PPI BD for next 20 days. After 5, 10, 30 days they are contacted and asked about symptoms and side effects of medication. Information will gather based on our check list and questionnaire. All patients who are tolerated more than 80% of treatment are included for evaluation and analysis. Four to five weeks after end of antibiotics treatment they will be send for UBT and results of HP eradication and side effects will analyse.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810152988N1**
Registration date: **2010-03-14, 1388/12/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-03-14, 1388/12/23

Registrant information

Name
Azita Ganji
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 1882 2327
Email address
ganjia@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of medical siences

Expected recruitment start date

2010-03-14, 1388/12/23

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing sequential treatment with classic triple therapy for helicobacter pylori eradication

Public title

Sequential therapy in Helicobacter pylori eradication

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with positive rapid urease test (RUT) who had indication of helicobacter eradication.
Exclusion criteria: history of HP eradication, patients on

PPI, history of allergic reaction to our medicine, history of any antibiotic in last 4 weeks, renal failure.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **130**

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
Ethics committee of Mashhad university of medical sciences

Street address
Danshgeh street

City
Mashhad

Postal code

Approval date
empty

Ethics committee reference number
88203

Health conditions studied

1

Description of health condition studied
Eradication of Helicobacter pylori

ICD-10 code
K27

ICD-10 code description
Peptic ulcer, site unspecified

2

Description of health condition studied
Eradication of Helicobacter pylori

ICD-10 code
K29

ICD-10 code description
Gastritis and duodenitis

Primary outcomes

1

Description
helicobacter pylori eradication

Timepoint
45th day

Method of measurement
Urease btreath test

Secondary outcomes

1

Description
side effects of treatment

Timepoint
day 5, 10, 30

Method of measurement
contact by phone and if needed visit in the clinic

Intervention groups

1

Description
Sequential treatment: omeprazole 20mg twice daily/Amoxicillin 1gr every 12 hours for first 5 day and in next 5 days, Omeprazole 20 mg /Clarithromycin 500 mg and Metronidazole 500 mg every 12 hours and for last 20 days just omeprazole 20 mg twice daily.

Category
Treatment - Drugs

2

Description
Classic treatment (triple therapy): omeprazole 20mg, amoxicillin 1 g, clarithromycin 500mg every 12 hours for 10 days and for last 20 days just omeprazole 20 mg twice daily.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza hospital

Full name of responsible person

Street address

City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
DR Jalil Tavakol afshari
Street address
Mashhad university of Medical siences, Ghoryshi building
City
Mashhad
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, Mashhad 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
Mashhad University of Medical Siences
Full name of responsible person
Azita Ganji
Position
Assistant professor
Other areas of specialty/work
Street address
Emam Reza Hospital
City
Mashhad
Postal code
Phone
+98 51 1882 2327
Fax
Email
ganjia@mums.ac.ir , azita_ganji@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashad University of medical siences
Full name of responsible person
Azita Ganji
Position
Assistant professor, Gastroentrologist
Other areas of specialty/work
Street address
Emam Reza Hospital
City
Mashhad
Postal code
Phone
+98 51 1882 2327
Fax
Email
ganjia@mums.ac.ir , azita_ganji@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad university of medical siences
Full name of responsible person
Azita Ganji
Position
Gastroenterologist
Other areas of specialty/work
Street address
Emam Reza Hospital
City
Mashhad
Postal code
Phone
+98 88 22327
Fax
+98 88 22327
Email
ganjia@mums.ac.ir , aita_ganji@yahoo.com
Web page address

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