Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of standard anti-Helicobacter pylori eradication regimen with and without N Acetylcysteine in patients with dyspepsia

Protocol summary

Summary

Objectives: Eradication of Helicobacter pylori which colonized the gastric mucous gel layer has an important role in the treatment of peptic ulcers, chronic gastritis and malt lymphoma. Favorable eradication regimes depend on different variables, including age, bacterial factors, antibiotic resistance patterns, health status of community and socioeconomic factors. Such variables especially antibiotic resistance is constantly changing. N-acetyl-cysteine is a powerful Sulfydryl compound with mucolytic properties that reduce gastric mucosal barrier and reducing the viscosity up to75% and increases delivery of antibiotics to the place of the microorganism. Design, setting and conduct: This study examines and compare the effect of adding 1.2 g N-Acetyl-cysteine daily for two weeks with standard four drug regimens (Amoxicillin 500 mg four times daiy, Bismuth subcitrate 120 mg four times daily, Omeprazole 20 mg twice daily and Clarithromycin 500 mg twice day) in the eradication of Helicobacter pylori. In the control group placebo will not be used. Participants: All patients between 17-80years with gastrointestinal symptoms and dyspepsia which refer to the Gastroenterology Clinics for endoscopy by a gastroenterologist recruited with full consent if Helicobacter pylori tests were positive (confirmed by histology, rapid urease test or stool antigen test). Exclusion criteria included: Patients previously received eradication of Helicobacter pylori treatment, presence of underlying disease such as cirrhosis, renal failure, severe cardiac disease, malignancy outside the GI tract, the need for simultaneous use of NSAIDs, the need for concomitant use of steroids, recent gastrointestinal bleeding, pregnancy or breast feeding. Intervention: Patients randomly assign in one of two standard anti-Helicobacter pylori eradication regimens with and without N Acetylcysteine. If the patients were taking more than 85 percent of drug considered drug tolerance. Main outcome: Eight weeks after termination of Helicobacter pylori eradication regimes, Helicobacter pylori stool antigen test performed to evaluate the effectiveness of the eradication of Helicobacter pylori. If Helicobacter pylori stool antigen test result was negative, successful eradication considered.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201078634N1**
Registration date: **2012-05-07, 1391/02/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-05-07, 1391/02/18

Registrant information

Name

Mehdi Zobeiri

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2012-01-20, 1390/10/30

Expected recruitment end date
2012-09-05, 1391/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of standard anti-Helicobacter pylori eradication regimen with and without N Acetylcysteine in patients with dyspepsia

Public title
Comparison of standard anti-Helicobacter pylori eradication regimen with and without N Acetylcysteine in patients with dyspepsia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria included: All patients with gastrointestinal symptoms and dyspepsia which refer to the Gastroenterology Clinics of Al-Zahra hospital, Noor, Poursina Hakim Research Center and Ardakan hospital for endoscopy by a gastroenterologist recruited with full consent if Helicobacter pylori tests were positive (confirmed by histology, Rapid urease test or stool antigen test). Exclusion criteria included: Patients previously received eradication of Helicobacter pylori treatment؛ Presence of underlying disease such as cirrhosis؛ Renal failure؛ Severe cardiac disease؛ malignancy outside of the GI؛ Age less than 17 and more than 80؛ Simultaneous use of NSAIDs؛ Concomitant use of steroids؛ Recent gastrointestinal bleeding؛ pregnancy or lactation.
Age
From **17 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
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 Isfahan University of Medical Sciences
Street address
Ethics Committee of Isfahan University of Medical Sciences, Vice chancellor for research, Isfahan University of Medical Sciences, HezarJarib St., Isfahan
City
Isfahan
Postal code
Approval date
2010-09-16, 1389/06/25
Ethics committee reference number
389226

Health conditions studied

1

Description of health condition studied
Dyspepsia
ICD-10 code
B98.0
ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases classified

Primary outcomes

1

Description
Helicobacter pylori eradication
Timepoint
Prior to and one month after intervention
Method of measurement
Stool antigen

Secondary outcomes

1

Description
Drug side effects
Timepoint
During and after drug consumption
Method of measurement
Visiting and call-chek list

2

Description
Drug tolerance
Timepoint
During drug consumption
Method of measurement

Visiting and call

Intervention groups

1

Description
Intervention group received standard treatment of anti H pylori which include Amoxicillin 500 mg four times daily, Bismuth citrate 120 mg four times daily, Omeprazole 20 mg twice daily, Clarithromycin 500 mg twice daily plus effervescent N Acetylcysteine 600 mg tablets 2 times a day per oral for 14 days.
Category
Treatment - Drugs

2

Description
Control group received standard treatment of anti H pylori which include Amoxicillin 500 mg four times daily, Bismuth citrate 120 mg four times daily, Omeprazole 20 mg twice daily, Clarithromycin 500 mg twice daily per oral for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
GI clinic of Azahra
Full name of responsible person
Dr Zobeiri
Street address
GI clinic of Azahra, Azahra hospital, Soffeh Boulevard, Isfahan, Iran
City
Isfahan

2

Recruitment center
Name of recruitment center
GI clinic of Noor hospital
Full name of responsible person
Street address
GI clinic of Noor hospital, Noor hospital, Next to Shahid Dastgheib Boulevard, Ostandari St., Isfahan, Iran
City
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3

Recruitment center
Name of recruitment center
Poursina Hakim Digestive Research Center
Full name of responsible person
Street address
Poursina Hakim Digestive Research Center, Second floor of Behesht building, opposite of Al Kareem mosque, Bozorgmehr St., Isfahan, Iran
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences
Full name of responsible person
Dr Peyman Adibi
Street address
Vice chancellor for research, Isfahan University of Medical Sciences, Isfahan University of Medical Sciences, Hezar Jarib St, Isfahan
City
Isfahan
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, Isfahan 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
Kermanshah University of Medical Sciences
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Assistant professor
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