Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of two treatment regimens with and without N-acetyl cysteine for eradication of Helicobacter pylori

Protocol summary

Summary

The objective of this controlled trial was to evaluate the efficacy of adding N- acetylcystein drug to the H. pylori eradication regimen in a sample population in Iranian patients. In this study, patients with dyspepsia who are referred for endoscopy to Imam Reza hospital affiliated to Kermanshah University of Medical Sciences and meet eligibility criteria will be enrolled. The patients referred in even days considered as the study group and after confirmation of H. pylori by rapid urease test and histology will receive the regimen of amoxicillin 1000 mg twice daily + clarithromycin 500mg twice daily + omeprazole 20 mg twice daily and those referred in odd days as the control group will receive the same regimen plus N- acetylcysteine 600 mg twice daily for two weeks. Four weeks after completion of the treatment, the same diagnostic procedures will be repeated in both groups. H. pylori eradication rates and drug side effects will be measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108197302N2**
Registration date: **2011-10-03, 1390/07/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-10-03, 1390/07/11

Registrant information

Name

Ali Asghar Keshavarz

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences, Vice-chancellor for Research and technology

Expected recruitment start date

2011-09-16, 1390/06/25

Expected recruitment end date

2011-12-16, 1390/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two treatment regimens with and without N-acetyl cysteine for eradication of Helicobacter pylori

Public title

Effect of N- acetyl cysteine on H.Pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having the indications of endoscopy, i.e. age over 50 years with symptoms of dyspepsia, individuals with less than 50 years of age who are resistant to a 4-week treatment with gastric acid inhibitors Exclusion criteria: not willing to undergo endoscopy; having a history of taking antibiotics, bismuth, or proton pump inhibitors in the two weeks prior to the visit; suffering from severe diseases such as renal failure, heart or liver disease, chronic use of anti-

inflammatory medications (either non steroidal or corticosteroids), history of surgery or known cases of extra- intestinal cancer, pregnancy, breast feeding

Age
From **15 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **115**

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
Ethic committee in research of vice- chancellor for research and technology, Kermanshah University o

Street address
Shahid Beheshti Boulevard, Kermanshah University of Medical Sciences,vice-chancellor of research and technology

City
Kermanshah

Postal code

Approval date
2009-09-15, 1388/06/24

Ethics committee reference number
21484/42/7/پ

Health conditions studied

1

Description of health condition studied
Dyspepsia

ICD-10 code
K30

ICD-10 code description
dyspepsia

Primary outcomes

1

Description
H.pylori eradication rate

Timepoint
4 weeks

Method of measurement
Urease breath test and histology

Secondary outcomes

1

Description
Drug side effects

Timepoint
4 weeks

Method of measurement
Checklist

Intervention groups

1

Description
Control group: Amoxicillin 1000mg twice daily, clarithromycin 500 mg twice daily,omeprazole 20 mg twice daily plus 600mg single dose of NAC for two weeks.

Category
Treatment - Drugs

2

Description
Intervention group: amoxicillin 1000 mg twice daily, clarithromycin 500 mg twice daily,omeprazole 20 mg twice daily for two weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam reza hospital

Full name of responsible person
Ali Asghar Keshavarz MD

Street address
Emam reza hospital, Kermanshah University of Medical Sciences

City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice – Chancellery of Research & Technology Affairs, Kermanshah University of Medical Sciences
Full name of responsible person
Dr Ghadiri,MD
Street address
Shahid Beheshti Boulevard
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice – Chancellery of Research & Technology Affairs, Kermanshah 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

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Name of organization / entity
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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