

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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)

##### Phone

+98 83 1724 4800

##### Email address

akeshavarz@kums.ac.ir

##### 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

**Contact****Name of organization / entity**

Emam reza hospital, Kermanshah University of  
Medical Sciences

**Full name of responsible person**

Ali Asghar Keshavarz

**Position**

Associate professor

**Other areas of specialty/work****Street address**

Department of gastroenterology,emam reza hospital

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Kermanshah

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### Person responsible for scientific inquiries

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### Person responsible for updating data

**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Other areas of specialty/work****Street address**

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**City**

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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*