

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jul 2026

### Assessment of efficacy of N-Acetylcysteine plus standard quadruple therapy regimen in comparison to standard quadruple therapy regimen for H. pylori infection eradication

#### Protocol summary

##### Summary

aim: if NAC is applied as an adjunct to standard therapy in H. pylori eradication, it may have an additive influence. design: clinical trial methods and materials: In this study, all patients with dyspepsia and with positive rapid urease test (RUT) will be enrolled. Patients randomized in one of two treatment groups: The experimental group was given amoxicillin (capsules, 1000 mg) bid (with breakfast and dinner), clarithromycin (capsules, 500 mg) bid (with breakfast and dinner), and omeprazole (capsules, 20 mg) bid (before breakfast and dinner), plus NAC 600 mg bid. The control group was given amoxicillin/clarithromycin/omeprazole the same as experimental group, plus placebo. In patients without peptic ulcer, omeprazole 20 mg once daily was continued for 2 weeks. But patients with peptic ulcer were treated for 4-6 additional weeks. Exclusion criteria: age<18 and >70, recent use of antibiotics, bismuth salts, or proton pump inhibitors (PPI), chronic use of nonsteroidal anti-inflammatory drugs or corticosteroids, gastric outlet obstruction, pregnancy, renal failure, gastric malignancy, and prior gastric surgery

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201605201155N24**  
Registration date: **2016-08-30, 1395/06/09**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-08-30, 1395/06/09

##### Registrant information

##### Name

Farahnaz Joukar

##### Name of organization / entity

Guilan University of Medical Sciences,  
Gastrointestinal and liver disease Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1553 5116

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

vice chancellor for Research of Guilan University of  
Medical Sciences

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2017-02-19, 1395/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of efficacy of N-Acetylcysteine plus  
standard quadruple therapy regimen in comparison to  
standard quadruple therapy regimen for H. pylori  
infection eradication

##### Public title

Assessment of efficacy of N-Acetylcysteine plus  
standard quadruple therapy regimen in comparison to  
standard quadruple therapy regimen for H. pylori  
infection eradication

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: All patients with peptic-like epigastric pain and dyspeptic symptoms, referred to the endoscopy unit and scheduled for upper GI endoscopy and with positive rapid urease test Exclusion criteria: age<18 and >70, recent use of antibiotics, bismuth salts, or proton pump inhibitors (PPI), chronic use of nonsteroidal anti-inflammatory drugs or corticosteroids, gastric outlet obstruction, pregnancy, renal failure, gastric malignancy, and prior gastric surgery

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: **46**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Gastrointestinal and Liver Disease Research Center of Guilan University of Medic

##### Street address

Gastrointestinal and Liver Diseases Research Center, Razi Hospital, Sardare Jangal Avenue, Rasht, Guilan province, Iran

##### City

Rasht

##### Postal code

4144895655

#### Approval date

2015-07-21, 1394/04/30

#### Ethics committee reference number

812

## Health conditions studied

### 1

#### Description of health condition studied

Helicobacter pylori

#### ICD-10 code

B98.0

#### ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

## Primary outcomes

### 1

#### Description

eradication of Helicobacter pylori

#### Timepoint

before initiate Intervention, two wk after finishing the intervention

#### Method of measurement

Urease breath test

## Secondary outcomes

### 1

#### Description

side effects

#### Timepoint

before initiating intervention, 2 wk after finishing the intervention

#### Method of measurement

physical examination

## Intervention groups

### 1

#### Description

The experimental group was given amoxicillin (capsules, 1000 mg) bid (with breakfast and dinner), clarithromycin (capsules, 500 mg) bid (with breakfast and dinner), and omeprazole (capsules, 20 mg) bid (before breakfast and dinner), plus NAC 600 mg bid.

#### Category

Treatment - Drugs

### 2

#### Description

(The control group was given amoxicillin/clarithromycin/omeprazole the same as experimental group, plus placebo. In patients without peptic ulcer, omeprazole 20 mg once daily was continued for 2 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Gastrointestinal and Liver Diseases Research Center

**Full name of responsible person**

Farahnaz Joukar

**Street address**

Gastrointestinal and Liver Diseases Research Center,  
Razi Hospital, Sardare Jangal Avenue

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research of Guilan University of  
Medical Sciences

**Full name of responsible person**

Dr Rasool Tabari KHomeirani

**Street address**

Sadati Street, Namjoo Street, Rasht ,Guilan,Iran

**City**

Rasht

**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 Guilan 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**

Gastrointestinal and Liver Disease Research  
Center(GLDRC)

**Full name of responsible person**

Farahnaz Joukar

**Position**

Assistant of Gastrointestinal and Liver Disease  
Research Center (GLDRC)

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

## Person responsible for scientific inquiries

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

Gastrointestinal and Liver Disease Research Center  
(GLDRC)

**Full name of responsible person**

Dr.Fariborz Mansour-Ghanaei

**Position**

Professor of Gastroenterology and Hematology  
Guilan, Chief of Gastrointestinal and Liver Disease  
Res

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## Person responsible for updating data

**Contact****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*