

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

info@gldrc.org

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

City

Rasht

Gastrointestinal and Liver Disease Research Center
(GLDRC), Razi Hospital, Sardar Jangal Ave, Guilan
province, IRAN

City

Rasht

Postal code**Phone**

+98 13133535116

Fax**Email**

F_jokar@gums.ac.ir

Web page address

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

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

Gastrointestinal and Liver Disease Research Center
(GLDRC), Razi Hospital, Sardar Jangal Ave, Guilan
province, Iran

City

Rasht

Postal code**Phone**

+98 13 1553 5116

Fax**Email**

ghanaei@gums.ac.ir

Web page address

www.gldrc.org

Person responsible for updating data

Contact**Name of organization / entity**

Gastrointestinal and Liver Disease Research Center

Full name of responsible person

Sara Mavaddati

Position

Bachelor of Cellular & Molecular Biology

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

Gastrointestinal and Liver Disease Research Center
(GLDRC), Razi Hospital, Sardar Jangal Ave, Guilan
province, IRAN

City

Rasht

Postal code**Phone**

00

Fax

Email

Mavaddati.sara@gmail.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