

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluating the efficacy of N-acetyl cysteine (NAC) in dyspeptic patients and negative *Helicobacter pylori* infection

Protocol summary

Study aim

We aim to evaluate the efficacy of NAC in improvement of dyspepsia symptoms in *H. Pylori* negative patients

Design

In this research, 88 patients with dyspepsia and *H. pylori* negative with inclusion criteria and not having exclusion criteria referring to Gastroenterology clinics will be included. Patients will be randomly allocated to pantaprazol with or without NAC groups and each patient will be given a specific code.

Settings and conduct

After patients selection, they will be randomly allocated to Pantaprazol with or without NAC groups. Patients in both groups will be treated for 8 weeks and will be evaluated before and after intervention for dyspepsia symptoms according to ROME III criteria and need for endoscopy after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with dyspepsia and *H. pylori* negative test. Exclusion criteria: Chronic use of NSAIDs or corticosteroids for more than a month; gastric outlet obstruction diagnosed in endoscopy; pregnancy (due to the complications); chronic kidney disease; GI malignancy; previous gastric surgery; patients with asthma or COPD receiving NAC.

Intervention groups

Patients will receive pantaprazol 40 mg daily with or without NAC 600 mg daily.

Main outcome variables

The main outcomes of the study are change in dyspepsia symptoms according to ROME III criteria and need for endoscopy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170716035126N3**

Registration date: **2018-02-17, 1396/11/28**

Registration timing: **prospective**

Last update: **2018-02-17, 1396/11/28**

Update count: **0**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

Afshin Habibzadeh

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3352 2391

Email address

a.habibzade@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of N-acetyl cysteine (NAC) in dyspeptic patients and negative *Helicobacter pylori* infection

Public title

Evaluating the efficacy of N-acetyl cysteine (NAC) in dyspeptic patients and negative Helicobacter pylori infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with the complaint of dyspepsia and negative H. pylori test

Exclusion criteria:

Chronic use of NSAIDs or corticosteroids for more than a month
Gastric outlet obstruction diagnosed in endoscopy
Pregnancy (due to the side effects)
Chronic kidney disease
GI malignancy
previous gastric surgery
Patients receiving NAC due to asthma or COPD

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyst

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized into two groups using random number blocks and using sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the person evaluating the treatment outcome will be blinded to the allocated groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medicine Sciences, Daneshgah St.,

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Approval date

2018-01-14, 1396/10/24

Ethics committee reference number

IR.ARUMS.REC.1396.208

Health conditions studied

1

Description of health condition studied

dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

Primary outcomes

1

Description

Dyspepsia symptoms

Timepoint

Before and 8 weeks after intervention

Method of measurement

Using ROME III criteria

2

Description

Need for endoscopy

Timepoint

8 weeks after intervention

Method of measurement

No change or deterioration of dyspepsia symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive pantaprazol 40 mg and NAC 600 mg daily

Category

Treatment - Drugs

2

Description

Control group: Patients will receive only pantaprazol 40 mg daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil Imam Khomeini Hospital

Full name of responsible person

Moharram Nokhah

Street address

Imam Khomeini Hospital, Ataei Ave.,

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Phone

+98 45 3352 2083

Email

dr.mnokhah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Masoud Entezari Asl

Street address

Ardabil University of Medical Science, Daneshgah St.,

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Phone

+98 45 3352 2083

Email

m.entezari@arums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Afshin Habibzadeh

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Imam Khomeini hospital, Ataei Ave.,

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3352 2391

Email

afshin.habibzadeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Nasser Hajavi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Imam Khomeini Hospital, Ataei ave.,

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3352 2391

Email

nhajavi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Moharram Nokhah

Position

Internal Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Imam Khomeini Hospital, Ataei ave.,

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3352 2391

Email

dr.mnokhah@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available