

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The role of N-acetyl Cysteine in the eradication of H.Pylori

Protocol summary

Study aim

The role of N-acetyl Cysteine in the eradication of H.Pylori

Design

This study will be double-blind and clinical trial. 167 patients with dyspepsia under the endoscopy will enter this study. We will divide in two groups randomly.

Settings and conduct

This study is double-blind and clinical trial. We divide in two groups randomly. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor. We will divide in two groups randomly. We treat patients with regime of standard by 4 drugs for 2 weeks in first group. We treat patients with regime of standard by 4 drugs and N-Acetylcysteine 600 milligram every 12 hours for 2 weeks in second group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 20 years, they have not already received the eradication regimen, patients who have not taken NAC in the last month Exclusion criteria: Pregnancy and breastfeeding, nausea and vomiting, lack of cooperation

Intervention groups

We treat patients with regime of standard 4 drugs (Clarithromycin - Amoxicillin - Omeprazole - Bismuth) for 2 weeks in first group. We treat patients with regime of standard 4 drugs and N-Acetylcysteine 600 milligram every 12 hours for 2 weeks in second group.

Main outcome variables

Eradication of Helicobacter infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N103**

Registration date: **2019-04-08, 1398/01/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-08, 1398/01/19**

Update count: **0**

Registration date

2019-04-08, 1398/01/19

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of N-acetyl Cysteine in the eradication of H.Pylori

Public title

The role of N-acetyl Cysteine in the eradication of H.Pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 20 years They have not already received the eradication regimen

Exclusion criteria:
Pregnancy and breastfeeding Nausea and vomiting Lack of cooperation

Age
From **20 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **167**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with random number table in division of groups in two groups A and B. Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we set the framework for our statistical society. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that, the numbers control the path. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers were used for intervention group and odd numbers were used for the control group. Allocation concealment: Numbered drug containers

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee

Arak University Of Medical Sciences

Street address
Research Center, Payambar Azam Complex, Basij Squre ,Sardasht,Arak

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2018-02-26, 1396/12/07

Ethics committee reference number
IR.ARAKMU.REC.1396.290

Health conditions studied

1

Description of health condition studied
Dyspepsia

ICD-10 code
K30

ICD-10 code description
Functional dyspepsia

Primary outcomes

1

Description
Eradication Helicobacter infection

Timepoint
4 weeks after treatment

Method of measurement
Urease respiratory test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We treat intervention group 4 drugs (Clarithromycin - Amoxicillin - Omeprazole - Bismuth)(Abidi Co) and N-Acetylcysteine (Ave Sina Co) 600 milligram every 12 hours for 2 weeks.

Category
Treatment - Drugs

2

Description
Control group: We treat patients with regime of standard by 4 drugs (Clarithromycin - Amoxicillin - Omeprazole - Bismuth)(Abidi Co) in 2 weeks for first group

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin Hospital
Full name of responsible person
Zahedin Kheiri
Street address
Sardasht, Basij square, Amiralmomenin hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Arjmandzadegan
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Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr Zahedin Kheiri
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Bahara Salmanzadeh

Position

Resident of internal medicine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Kheiri

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments