

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the additive therapeutic effect of N-acetyl cysteine (NAC) on the treatment of persistent Helicobacter pylori (H.pylori) infection

Protocol summary

Study aim

1- Determination of the additive therapeutic effect of N acetylcysteine in the treatment of persistent Helicobacter infection. 2- determinate and compare side effect in 2 intervention and control groups

Design

This study is interventional, which patients after signing the consent enter in study and then accidentally one by one take standard treatment or standard with NAC and then results of treatment are compared.

Settings and conduct

The study is performed on the patients who refer to shahid Beheshti hospital and Helal Ahmar clinic in Yasuj and becomes 2 groups for treatment and then are compared.

Participants/Inclusion and exclusion criteria

The patient who used chronically NSAID or corticosteroid or have gastric outlet obstruction or pregnancy or renal failure or gastric cancer or precious surgery or use bismuth in first treatment extract of study and the patient who used chronically NSAID or corticosteroid or have gastric outlet obstruction or pregnancy or renal failure or gastric cancer or precious surgery or use bismuth in first treatment extract of study.

Intervention groups

The patient who had persistent helicobacter and use standard and NAC treatment for it

Main outcome variables

Side effects; stool Ag

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190326043119N1**

Registration date: **2020-02-28, 1398/12/09**

Registration timing: **retrospective**

Last update: **2020-02-28, 1398/12/09**

Update count: **0**

Registration date

2020-02-28, 1398/12/09

Registrant information

Name

Fatemeh Gerist

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 4536

Email address

fagerist2013@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-09-01, 1398/06/10

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2019-09-01, 1398/06/10

Trial completion date

2019-09-01, 1398/06/10

Scientific title

Evaluation of the additive therapeutic effect of N-acetyl cysteine (NAC) on the treatment of persistent Helicobacter pylori (H.pylori) infection

Public title

Effect of N-acetyl cysteine (NAC) in treatment of persistent Helicobacter infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patients who refer to shahid Beheshti hospital and Helal e Ahmar clinic who take one episode treatment of H.pylori and did not respond in endoscopy or noninvasive tests such as urease test or stool Ag who we told them persistent h pylori patient

Exclusion criteria:

The patients who used chronically NSAID or corticosteroid Have gastric outlet obstruction Pregnancy Renal failure Gastric cancer Precious surgery Use bismuth in first treatment extract of the study

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **126**

Actual sample size reached: **121**

Randomization (investigator's opinion)

Randomized

Randomization description

Random permuted blocks was used for randomization with blocks of the size of that after every 4 patient there was an equal number assigned to each treatment for each block one of the arrangements (ccii ,cici,icci,iicc,good,ciic) was randomly chosen.(c=control,i=intervention)

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**

Ethics committee of Yasuj University of Medical Sciences

Street address

Emam Sajad hospitalm, Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7541994579

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.YUMS.REC.1397.117

Health conditions studied**1****Description of health condition studied**

Persistent helicobacter infection

ICD-10 code

B99- B99

ICD-10 code description

Certain infectious and parasitic diseases

Primary outcomes**1****Description**

Negative response of stool Ag

Timepoint

Stool Ag 4 weeks after treatment

Method of measurement

Stool Ag in laboratory

Secondary outcomes**1****Description**

Side effects

Timepoint

After 2 weeks treatment

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intervention group: which used for treatment them standard and NAC we want to compare treatment ratio in both group which take NAC and did not take that we used NAC 600mg bid for 14 day in intervention group.

Category

Treatment - Drugs

2**Description**

Control group: who take standard treatment for persistent helicobacter

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Shahid beheshti hospital. Helal Ahmar clinic .

Full name of responsible person

Dr Farshad Ferydooni

Street address

Emam Sajjad hospital

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Kohgilouyeh-va-Boyrahmad

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Phone

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Email

Fagerist2013@gmail.com

Full name of responsible person

Dr Farshad Ferydooni

Position

Associate of professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Dr Mary oryad

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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

Yasouj 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**

Yasouj University of Medical Sciences

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Dr Farshad Fereydooni

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Dr Fatemeh Gerist

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The information is private.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable