Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 helicobacterand 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 arreagments (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 labratory

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
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7541994579
Phone
+98 74 3322 0165
Email
Fagerist2013@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr Mary oryad
Street address
Emam Sajad hospital yasuj
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7541994579
Phone
+98 74 3322 0165
Email
Fagerist2013@gmail.com
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
Full name of responsible person
Dr Farshad Ferydooni
Position
Associate of professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Emam Sajad hospital
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7541994579
Phone
+98 74 3322 0165
Email
Fagerist2013@gmail.com

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
Street address
Emam Sajad hospital
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7541994579
Phone
+98 74 3322 0164
Email
Fagerist2013@gmail.com

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
Street address

Emam Sajad hospital
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7541994579
Phone
+98 74 3322 0165
Email
Fagerist2013@gmail.com

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