

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Effect of N-Acetyl cysteine on the success rate of H.pylori eradication

#### Protocol summary

##### Summary

H.pylori eradication (HP) is the most common chronic bacterial infection in humans. HP is a Gram-negative spiral Microaerophilic organism. This study will be done as clinical trial and the aim of this study was comparing the administration of NAC as a pre-treatment before starting eradication regimen HP with the control group in terms of success. The sample size given that the response to standard therapy in the treatment of Helicobacter pylori According to sources, was 115 samples for each group and a total of 230 samples were estimated. Groups of patients referred to the gastroenterology clinic and endoscopy will be selected. All patients with more than 20 years of participation in the plan who are positive for HP and has eradication indication and do not use the drugs effective on HP, were randomly divided into two treatment and control groups. The Patients will be evaluated who at the time of studying have an indication for eradication of H pylori eradication and has not previously received any eradication regimen., and they also have NAC consumption during the last month. Exclusion criteria included a history of gastrectomy, gastric cancer includes adenocarcinoma and lymphoma, previous allergic reaction to antibiotics (amoxicillin and clarithromycin), NAC and proton pump inhibitors For example (omeprazole), pregnant and lactating women, concurrent severe illness, phenyl ketoneuria, taking antibiotics or NAC now or in the past month and is patient's dissatisfaction. Patients will be randomly divided into two groups. the treatment group are pretreated with NAC for the 600 mg 2 times a day for a week and then standard triple therapy alone (amoxicillin 1000 mg 2 times a day, clarithromycin 500 mg two times daily and omeprazole 20 mg 2 times a day). The control group are treated with standard triple therapy. The level of response to treatment in each category are calculated and compared. Variables included age, gender, current smoking, alcohol consumption, eradication indication regimen and complications during and up to one week

after treatment and response to treatment. Response to treatment (eradication of Helicobacter pylori) will be evaluated by stool antigen test for a month at the end of treatment and at least 2 weeks after discontinuation of proton pump inhibitors (PPI). The required data in both groups will be collected through interviews and tests.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012121511738N2**

Registration date: **2016-05-17, 1395/02/28**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-17, 1395/02/28

##### Registrant information

###### Name

Kurosh Masnadi Shirazi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1334 7554

###### Email address

masnadik@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-04-01, 1395/01/13

##### Expected recruitment end date

2017-03-20, 1395/12/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of N-Acetyl cysteine on the success rate of H.pylori eradication

**Public title**

Effect of N-Acetyl cysteine on the success rate of H.pylori eradication

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: patients older than 20 years old, HP positive patients at the time of an injection molded pylori eradication indicated they have not previously received eradication regimen, the patients who have NAC in past month. Exclusion criteria: history of gastrectomy, gastric cancer includes adenocarcinoma, previous allergic reaction to antibiotics (amoxicillin and clarithromycin), NAC and proton pump inhibitors (omeprazole), pregnant and lactating women, concurrent severe illness, phenyl ketone Avery, taking antibiotics or NAC now or in the past month and is patient's dissatisfaction.

**Age**

From **20 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **230**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not 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 Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences, Golgasht Street, Tabriz

**City**

Tabriz

**Postal code****Approval date**

2016-02-20, 1394/12/01

**Ethics committee reference number**

TBZMED.REC.1394.1186

**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**

The success rate of H pylori eradication regimen

**Timepoint**

One month after treatment

**Method of measurement**

Test

**Secondary outcomes**

empty

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

the treatment group are pretreated with NAC groups underfor the 600 mg 2 times a day for a week and then standard triple therapy (amoxicillin 1000 mg 2 times a day, clarithromycin 500 mg two times daily and omeprazole 20 mg 2 times a day).

**Category**

Treatment - Drugs

**2****Description**

Control group treated with standard triple therapy (amoxicillin 1000 mg 2 times a day, clarithromycin 500 mg two times daily and omeprazole 20 mg 2 times a day) are placed.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinic for Gastroenterology and Endoscopy  
Department of Imam Reza

##### Full name of responsible person

Dr.Said Mansouri

##### Street address

Department of Gastroenterology, Imam Reza  
Hospital, Gate University, Tabriz, East Azarbaijan

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research of Tabriz University of  
Medical Sciences

##### Full name of responsible person

Dr. Mohammad Reza Rashidi

##### Street address

Vice chancellor for Research of Tabriz University of  
Medical Sciences,Tabriz University of Medical  
Sciences, Golgasht Street, Tabriz

##### City

Tabriz

##### 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 Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr.Korosh Masnadi Shirazi

##### Position

Gastroenterologist, Assistant Professor

##### Other areas of specialty/work

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## Person responsible for updating data

#### Contact

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**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*