

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of citric acid on UBT results in dyspeptic patients on PPI and positive H.Pylori

Protocol summary

Summary

Helicobacter pylori infection has a significant role in peptic ulcer(stomach and duodenum) , gastric cancer (adenocarcinoma, Maltoma) and chronic gastritis . Urea Breathing Test (UBT) is easy, safe, noninvasive method , because of high accuracy , it's used for early detection and also is detection method for after treatment of H.pylori infection . With due attention to cases of false negative urea breath test following the use of PPI, we intended to study effect of citric acid to reduce false-negative cases , with this insight , the PPI decreases gastric acidity and caused to inhibitory effects on H. Pylori infection but citric acid increases gastric acidity . Dyspepsia patients referred to the gastroenterology clinic of Razi Hospital, which H. Pylori with one of the methods (UBT, RUT, Stool antigen, Histology, serology) is known, enter to this study. Firstly patient profile form , filled consent and inclusion criteria included : age $\geq$ 18 years , detection of Helicobacter pylori infection , start treatment with PPI and exclusion criteria included : the history of previous gastric surgery , antibiotics consumption during 4 weeks before the first UBT test or during the study period , participation in a clinical study during 30 days before the screening visit , other considerable clinical disorders that researcher postulates patient is not eligible , taking H2 blocker or PPI, 2 weeks before the study, pregnancy , history of recent peptic ulcer and esophagitis , prior therapy , history of chronic liver and renal disease are examined . Urea breath test was performed for all patients if be positive , patients are included in this study then 14-day treatment period for all runs . In 13-12 days, patients are divided into two groups : urea breath test is performed in group 1 with concurrent administration of 4g of citric acid and in group 2 done without administration of citric acid . Again on days 14-15th , urea breath test is done without citric acid in group 1 and with 4g citric acid in group 2 . The results of urea breath test are studied either parallel or before and after (cross) in both study groups .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105221155N12**

Registration date: **2011-08-14, 1390/05/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-14, 1390/05/23

Registrant information

Name

Farahnaz Joukar

Name of organization / entity

Guilan University of Medical Sciences,
Gastrointestinal and liver disease Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 1553 5116

Email address

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Recruitment status

Recruitment complete

Funding source

Vince chancellor for research Guilan university of medical sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of citric acid on UBT results in dyspeptic patients on PPI and positive H.Pylori

Public title
Evaluation of the effect of citric acid on UBT results in dyspeptic patients on PPI and positive H.Pylori

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria: Age $\geq$ 18 years ; Signed a consent form ; Detection of Helicobacter pylori infection ; start treatment with PPI Exclusion criteria: The history of previous gastric surgery ; Antibiotics consumption during 4 weeks before the first UBT test or during the study period ; Participation in a clinical study during 30 days before the screening visit ; Other considerable clinical disorders that researcher postulates patient is not eligible Taking H2 blocker or PPI ; 2 weeks before the study, Pregnancy ; History of recent peptic ulcer and esophagitis ; Prior therapy ; History of chronic liver and renal disease

Age
From **18 years** old to **100 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

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

Guilan University of Medical Sciences. Ethics Committee Gastrointestinal and Liver Diseases Research

Street address

Sardar Jangal Ave, Gastrointestinal and Liver Diseases Research Center, Razi Hospital, Rasht, Iran

City
Rasht

Postal code
955655-41488

Approval date
2011-05-26, 1390/03/05

Ethics committee reference number
160/ش

Health conditions studied

1

Description of health condition studied

dyspepsia

ICD-10 code

k30

ICD-10 code description

Indigestion

Primary outcomes

1

Description

Urease breath test with administration 4g of citric acid

Timepoint

2 days

Method of measurement

UBT

2

Description

Urease breath test without administration 4g of citric acid

Timepoint

2 days

Method of measurement

UBT

Secondary outcomes

empty

Intervention groups

1

Description

Group 1 : In during 12-13th days of PPI treatment , urease breath test is done with coadministration 4g of citric acid and in during 14-15th days it's done without administration of citric acid .

Category

Diagnosis

2

Description

Group 2 : In during 12-13th days of PPI treatment , urease breath test is done without administration of citric

acid and in during 14-15th days it's done with administration of 4g of citric acid .

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal clinic of Razi hospital

Full name of responsible person

Farahnaz Joukar

Street address

Gastrointestinal and Liver Diseases Research Center,
Razi Hospita, Sardare Jangal Avenue

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bidar Taban Ariya (BTA)

Full name of responsible person

Mr. Ali Mohammad Rafat Zand

Street address

No.1831 , unit 37 , Kargare Shomali Avenue ,Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bidar Taban Ariya (BTA)

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

Gastrointestinal and Liver Disease Research Center(GLDRC)

Full name of responsible person

Farahnaz Joukar

Position

assistant of gastrointestinal and liver disease

research center (GLDRC)

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gastrointestinal and Liver Disease Research Center (GLDRC)

Full name of responsible person

Dr.Fariborz Mansour-Ghanaei

Position

Head / Full Professor of Internal Medicine & Gastroenterology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Gastrointestinal and liver disease research center

Full name of responsible person

Dr. Maryam Bakhshandeh

Position

Researcher

Other areas of specialty/work

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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