

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison the eradication rate of Helicobacter pylori (HP) between standard triple therapy regime and licorice root extract adding to triple therapy regime in patients with helicobacter pylori infection

Protocol summary

Summary

Goal of study: The goal of this study is consideration of the eradication rate of Helicobacter Pylori (HP) through standard triple therapy regime in comparison with adding licorice root extract to this regime. Designing of study: Randomized, clinical trial. Inclusion criteria to study: if all patients during endoscopic procedure with have positive rapid urease test (RUT), providing that not having the following condition: pregnancy! Previous usage Antiacid or bismuth during recent a month ! Gastrointestinal (GI) bleeding: the usage of alcohol or substance ! advanced chronic disease. Exclusion criteria from study: lack of willingness to continue the treatment! suffering the illness that needs to consume another drug. Sample size: 120 patient. Methods & Intervention: patient with gastric disorder who need endoscopic procedure and having positive RUT for HP entering into this study and divided into 2 groups. First group(A) are treated by Clarithromycin (500 mg twice a day) + Amoxicillin (1 gr twice a day) + Omeprazole (20 mg twice a day) for 2 weeks and second group(B) are treated by licorice root extracts (D-Reglis 1 tab twice a day) adding to previous regime for the same duration. After finishing the main period of treatment they receive maintaining 4 weeks by omeprazole. Following two weeks of not taking any type of medicine then every patient is tested by stool antigen. Ultimately eradication rate of HP are compare in two groups. Intervention time: 2 weeks Primary outcome: Compare eradication of HP infection by stool antigen of HP between 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061718124N1**
Registration date: **2015-06-21, 1394/03/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-21, 1394/03/31

Registrant information

Name

Ali Akbar Hajiaghamohammadi

Name of organization / entity

Metabolic Diseases Research Center, Qazvin
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical
Sciences

Expected recruitment start date

2015-06-19, 1394/03/29

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the eradication rate of Helicobacter pylori

(HP) between standard triple therapy regime and licorice root extract adding to triple therapy regime in patients with helicobacter pylori infection

Public title

The consideration of the effectiveness of licorice root extract adding to triple therapy regime of Helicobacter Pylori

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria to study: if all patients during endoscopic procedure with have positive rapid urease test (RUT), providing that not having the following condition: pregnancy; Previous usage Antacid or bismuth during recent a month ; Gastrointestinal (GI) bleeding or any complication of peptic ulcer disease (PUD) ; the usage of alcohol or substance ; advanced chronic disease: Diabetes mellitus, Hypertension, Cirrhosis, Cerebrovascular attack, Coronary artery disease & gastric cancer. Exclusion criteria from study: lack of willingness to continue the treatment; lack of willingness to complete the period of treatment ;suffering the illness that needs to consume another antibiotic or non steroidal anti inflammatory drugs (NSAIDs) .

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Ethics committee of Qazvin University of Medical Sciences

Street address

Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar Blvd., Qazvin, iran

City

Qazvin

Postal code

Approval date

2015-01-08, 1393/10/18

Ethics committee reference number

9670/20/28

Health conditions studied

1

Description of health condition studied

Helicobacter pylori infection

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori

Primary outcomes

1

Description

Stool antigen of HP

Timepoint

Two weeks after ending period of treatment

Method of measurement

Laboratoriaf

Secondary outcomes

empty

Intervention groups

1

Description

Clarithromycin (500 mg twice a day) + Amoxicillin (1 gr twice a day) + Omeprazole (20 mg twice a day) for 2 weeks. After finishing the main period of treatment they receive maintaining 4 weeks by omeprazole only

Category

Treatment - Drugs

2

Description

Intervention group: licorice root extracts (D-Reglis 1 tab twice a day) adding to Clarithromycin (500 mg twice a day) + Amoxicillin (1 gr twice a day) + Omeprazole (20 mg twice a day) for 2 weeks. After finishing the main period of treatment they receive maintaining 4 weeks by omeprazole only

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital Specialty Clinic Qazvin

Full name of responsible person

Dr. Sedighe Reisian

Street address

velayat hospital, 22 bahman blvd, elahiye alley,
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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of
Medical Sciences

Full name of responsible person

Dr. Taghi Naserpoor

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Vice chancellor for research, Qazvin University of
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Qazvin

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, Qazvin 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**

Metabolic Diseases Research Center, Qazvin
University of Medical Sciences, Qazvin, Iran

Full name of responsible person

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Position

Resident of Internal Medicine

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Web page address

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