# 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 Antiacid 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, qazvin, iran

**City**
Qazvin

## 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

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

**City**
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**
Dr. Sedighe Reisian

**Position**
Resident of Internal Medicine

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**
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**Position**
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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*