

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of adding garlic extract to standard treatment regime of helicobacter pylori

#### Protocol summary

##### Summary

This is a randomized non-blinded clinical trial to assess the effect of adding garlic extract to the standard three-drug treatment of helicobacter pylori. The study population consists of dyspeptic patients referred to gastroenterology clinic of Boali Hospital whose Rapid Urease Test are positive in endoscopy. Patients with acute gastrointestinal bleeding or who have been recently treated with antibiotics or proton pump inhibitors are excluded from the study. Sampling will begin from 2012-6-21 and sampling method is serial. Patients are randomly allocated to treatment and control groups. The base of treatment is Clarithromycine+ Amoxicillin+ Pantoprazol and in the treatment group garlic is added to this regime. 37 patients are recruited in each group. The efficacy of treatment is assessed by Urea Breathing Test 6 weeks following end of treatment. Data will be gathered by checklists filled by the physicians and analyzed and presented in bars, charts and tables. The most important ethical issue is providing the basic required treatment for patients which is achieved by the standard treatment done in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109187493N2**

Registration date: **2012-06-02, 1391/03/13**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-06-02, 1391/03/13

##### Registrant information

Name

Reza Gholami

##### Name of organization / entity

Ghazvin University of Medical Sciences, Boali Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 1333 2930

##### Email address

rgholami@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Qazvin University of Medical Sciences, Deputy of Research

##### Expected recruitment start date

2012-06-21, 1391/04/01

##### Expected recruitment end date

2012-10-22, 1391/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of adding garlic extract to standard treatment regime of helicobacter pylori

##### Public title

The effect of garlic on helicobacter pylori treatment

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Signs of dyspepsia or peptic ulcer; Positive rapid urease test Exclusion criteria: Antibiotic therapy during the last month; Acute GI bleeding; Proton pump inhibitor treatment during the last month

##### Age

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 74

**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**

Qazvin University of Medical University

**Street address**

Daneshgah Boulevard, Qazvin

**City**

Qazvin

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

2011-05-17, 1390/02/27

**Ethics committee reference number**

28/20/4413

**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

**Primary outcomes****1****Description**

Helicobacter Pylori Eradication

**Timepoint**

6 weeks following end of treatment

**Method of measurement**

Urea Breathing Test

**Secondary outcomes**

empty

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

Intervention group: Amoxicillin 1 gram twice daily + Clarithromycine 500 mg twice daily + Pantoprazol 40 mg twice daily + Garlic daily

**Category**

Treatment - Drugs

**2****Description**

Control group: Amoxicillin 1 gram twice daily + Clarithromycine 500 mg twice daily + Pantoprazol 40 mg twice daily

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Boali Hospital

**Full name of responsible person**

Reza Gholami

**Street address**

Boali Street, Boali Hospital, Qazvin

**City**

Qazvin

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Reza Gholami

**Street address**

Daneshgah Boulevard, University of Medical Sciences Campus, Qazvin

**City**

Qazvin

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Reza Gholami

**Position**

Internal Medicine Resident

**Other areas of specialty/work****Street address**

Boali Street, Boali Hospital, Qazvin

**City**

Qazvin

**Postal code****Phone**

+98 28 1333 2932

**Fax****Email**

rgholami@qums.ac.ir

**Web page address****City**

Qazvin

**Postal code****Phone**

+98 28 1335 6696

**Fax****Email**

ahmohammadi@qums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Reza Gholami

**Position**

Internal Medicine Resident

**Other areas of specialty/work****Street address**

Boali Street, Boali Hospital, Qazvin

**City**

Qazvin

**Postal code****Phone**

+98 28 1333 2930

**Fax****Email**

rgholami@qums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Ali Akbar Hajaghamohammadi

**Position**

Gastroenterologist, Associate professor

**Other areas of specialty/work****Street address**

Boali Street, Boali hospital, Qazvin

**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*