Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 refered 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 anlyzed 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: Antiboitic 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 Boulvard, 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
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Daneshgah Boulvard, University of Medical Sciences Campus, Qazvin
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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
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Person responsible for updating data

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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