

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of the efficacy of addition of Cinnamon powder and placebo in eradication of Helicobacter Pylori infection, a clinical trial.

#### Protocol summary

##### Summary

**Objectives:** The goal of this study is comparing the addition of cinnamon powder and placebo to the conventional treatment of Helicobacter Pylori infection.

**Study design:** Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

**Setting and conduct:** Eligible patients in the study will randomly allocate to intervention and control groups. The sample size is 76 patients in each group. The patients, executive researcher and the chief colleague will not aware of allocation of patients to intervention and control groups.

**Participants:** In this study the inclusion criteria will be the Patients with dyspepsia; nosea; vomiting and epigastric pain attending the gastrointestinal clinic of Velayat hospital and infectious diseases clinic of Bualisina hospital; with positive evidence of Helicobacter Pylori infection (stool antigen test). The exclusion criteria will be HIV infection ; known cases of malignancies.

**Intervention:** In this study, H. Pylori triple therapy regimen (clarithromycin + amoxicillin + omeprazole) will be administered to both the intervention and control groups for two weeks. In the intervention group, 400 mg Cinnamon powder in capsules will be added to the basic regimen in the twice daily schedule. In controls placebo capsules appeared quite similar to Cinnamon capsules will be prescribed with the same schedule. main outcome variables: Helicobacter pylori stool antigen performed 6 weeks after the completion of treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201505032276N2**  
Registration date: **2015-08-01, 1394/05/10**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-08-01, 1394/05/10

##### Registrant information

###### Name

Behzad Bijani

###### Name of organization / entity

Qazvin University of Medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 1335 4808

###### Email address

bbijani@qums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

##### Expected recruitment start date

2015-06-22, 1394/04/01

##### 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 of the efficacy of addition of Cinnamon powder and placebo in eradication of Helicobacter Pylori infection, a clinical trial.

##### Public title

Effect of cinnamon in the treatment of Helicobacter Pylori

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Patients with dyspepsia; nosea; vomiting; epigastric pain attending gastrointestinal clinic of Velayat hospital and infectious diseases clinic of Bualisina hospital with positive evidense of Helicobacter Pylori infection (stool antigen test). Exclusion criteria: HIV infection; known cases of malignancies.

### Age

No age limit

### Gender

Both

### Phase

2-3

### Groups that have been masked

No information

### Sample size

Target sample size: 152

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

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 and Health Servises

##### Street address

5, Bahonar Blvd, Qazvin University of Medical Sciences and Health Servises

##### City

Qazvin

##### Postal code

59811-34197

#### Approval date

2015-03-16, 1393/12/25

#### Ethics committee reference number

28/20/10039

## Health conditions studied

### 1

#### Description of health condition studied

helicobacter pylori B98.0

#### ICD-10 code

B98.0

## ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

## Primary outcomes

### 1

#### Description

negative result of stool antigen of Helicobacter Pylori

#### Timepoint

6 weeks after the end of treatment

#### Method of measurement

Checking of H.Pylori stool antigen

## Secondary outcomes

### 1

#### Description

Oral ulcer

#### Timepoint

During, end and till 6 weeks after end of treatment

#### Method of measurement

Patient report

### 2

#### Description

Epigasteric pain

#### Timepoint

During, end and till 6 weeks after end of treatment

#### Method of measurement

Patient report

### 3

#### Description

Skin rash

#### Timepoint

During, end and till 6 weeks after end of treatment

#### Method of measurement

Patient report

### 4

#### Description

diarrhea

#### Timepoint

During, end and till 6 weeks after end of treatment

#### Method of measurement

Patient report

## Intervention groups

### 1

#### Description

Intervention group: clarithromycin 500 mg BD+ amoxicillin 1g BD+ omeprazole 20 mg BD + 400 mg Cinnamon powder in capsules BD for two weeks. (oral)

#### Category

Treatment - Drugs

2

### Description

Control group: clarithromycin 500 mg BD+ amoxicillin 500 mg BD+ omeprazole 20 mg BD + placebo capsules appeared quite similar to Cinnamon capsules (twice daily) for two weeks. (oral)

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Gastrointestinal Clinic, Velayat Hospital

#### Full name of responsible person

Arash Miroliaee

#### Street address

2, Velayat St, Minoodar Blvd

#### City

Qazvin

2

### Recruitment center

#### Name of recruitment center

Infectious diseases Clinic, Bualisina Hospital

#### Full name of responsible person

Behzad Bijani

#### Street address

112, Buali St

#### City

Qazvin

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice Chancellor for Research, Qazvin University of Medical Sciences and Health Services

#### Full name of responsible person

Dr Taghi Naserpour

#### Street address

15, Shahid Bahonar Blvd, Vice Chancellor for Research, Qazvin University of Medical Sciences and Health services

#### 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 and Health Services

### 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 and health Services

#### Full name of responsible person

Fatemeh Homayuni

#### Position

resident

#### Other areas of specialty/work

#### Street address

112, Buali St, Bualisina Hospital

#### City

Qazvin

#### Postal code

#### Phone

+98 28 3333 2930

#### Fax

#### Email

homauni.h@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Qazvin University of Medical Sciences and health Services

#### Full name of responsible person

Behzad Bijani

#### Position

Assistant professor, Infectious Diseases Specialist

#### Other areas of specialty/work

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112, Buali St, Bualisina Hospital

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#### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences and health  
Services

**Full name of responsible person**

Behzad Bijani

**Position**

Assistant Professor, Infectious Diseases

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

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**Postal code****Phone**

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**Fax****Email**

bbijani@qums.ac.ir; dr.bijani@gmail.com

**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*