Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2015-06-22, 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 (twise 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 Miroliayee
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Qazvin University of Medical Sciences and Health Servises
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
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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
Vice Chancellor for Research, Qazvin University of Medical Sciences and Health Servises
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 Servises
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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