

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of cinnamon extract as an adjuvant therapy in eradication of *Helicobacter pylori* in patients with *Helicobacter pylori*

Protocol summary

Study aim

Determination of the effect of Cinnamon extract as the additional treatment of *Helicobacter Pylori*

Design

A double-blind, randomized clinical trial with the control group

Settings and conduct

Patients referred to the gastroenterology clinic of Beheshti Hospital in Hamadan. Blinding is done for researcher, physician, pharmacist and the data analyzer

Participants/Inclusion and exclusion criteria

Inclusion criteria: Dyspepsia symptoms, positive evidence of *Helicobacter pylori* during biopsy. Exclusion criteria: upper gastrointestinal (Duodenal) bleeding, pregnancy and lactation, liver disorders, renal failure and heart failure, history of allergy to the drugs under study and cinnamon, previous treatment of *Helicobacter Pylori*, corticosteroid and bismuth consumption, history of alcohol use

Intervention groups

In the treatment group, the cinnamon extract will be added to the basal diet in the form of a 40 mg-capsule twice a day. In the control group, placebo capsules which are the same as cinnamon capsules in appearance and contain starch are given through a 40mg-capsule twice a day.

Main outcome variables

Eradication of *Helicobacter Pylori*

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121114011469N3**

Registration date: **2018-08-20, 1397/05/29**

Registration timing: **prospective**

Last update: **2018-08-20, 1397/05/29**

Update count: **0**

Registration date

2018-08-20, 1397/05/29

Registrant information

Name

Arezou Karampourian

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0572

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-21, 1397/05/30

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of cinnamon extract as an adjuvant therapy in eradication of *Helicobacter pylori* in patients with *Helicobacter pylori*

Public title

Effect of cinnamon in treatment of gastric ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Dyspepsia symptoms Positive test for Helicobacter pylori at biopsy

Exclusion criteria:
Duodenal gastrointestinal bleeding Pregnancy and lactation Liver disorders, Kidney failure, Heart failure History of allergy to the drugs under study and cinnamon Previous treatment of Helicobacter Pylori Current use of corticosteroids and Bismuth History of alcohol consumption

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyst

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients eligible for inclusion in the study will be allocated to two treatment and control groups using random numbers and two color cards.

Blinding (investigator's opinion)
Double blinded

Blinding description
Researcher, physician, medicine deliverer and the data analyzer will not know the allocation of the patient to the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Mardom Blvd.

City

Hamadan

Province

Hamadan

Postal code

6834568

Approval date

2018-06-09, 1397/03/19

Ethics committee reference number

IR.UMSHA.REC.1397.135

Health conditions studied

1

Description of health condition studied

Peptic ulcer

ICD-10 code

K27

ICD-10 code description

Peptic ulcer, site unspecified

Primary outcomes

1

Description

Eradication of Helicobacter Pylori

Timepoint

Three months after initiation of treatment

Method of measurement

Urease respiratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the treatment group, the cinnamon extract will be added to the basal diet in the form of 40 mg capsules , twice a day for 14 days.

Category

Treatment - Drugs

2

Description

Control group: In the control group, placebo 40 mg capsules, with a completely similar appearance of cinnamon capsules and containing starch, twice a day for 14 days are given.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology clinic of Beheshti Hospital in Hamadan

Full name of responsible person

Ghazal Imani
Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Research and Technology Deputy head
Street address
Mardom Blvd
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6856789
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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

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Imani Ghazal
Position

Pharmacy student
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
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Position
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Person responsible for updating data

Contact

Name of organization / entity
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total data after unidentifiable participants can be shared.

When the data will become available and for how long

After the end of the study

To whom data/document is available

Researchers working in academic centers, as well as those engaged in the industry, can apply for them.

Under which criteria data/document could be used

For the treatment of patients

From where data/document is obtainable

Email address

What processes are involved for a request to access data/document

Requesting information is possible through the author's email at the end of the study.

Comments