

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Oct 2026

Evaluation of cyclodextrin and propolis complex as adjuvant treatment in patients with *Helicobacter pylori*

Protocol summary

Study aim

Preparation beta-cyclodextrin propolis complex capsules and evaluation role of them as adjuvant therapy in helicobacter pylori infected patients.

Design

Randomized, blinded, parallel group trial, phase 3 on 100 patients.

Settings and conduct

Patients with symptoms of dyspepsia and a positive biopsy test will go to Tamin Ejtemaei or Atiye Hospitals and after giving informed consent, they will be divided into two treatment and control groups by block randomization. the patient, doctor and student researcher are blinded. The mentioned drug regimens will started for both groups, and after two months, the results are checked with the help of a questionnaire and fecal antigen test in terms of symptom improvement and bacterial eradication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients between 18 and 80 years old with symptoms of dyspepsia and a positive *Helicobacter* biopsy sample. Exclusion criteria: people with duodenal gastrointestinal bleeding, pregnant and lactating women, patients with liver disorders, kidney failure, heart failure and drug sensitivity to any of the studied drugs, patients with a history of *Helicobacter pylori* therapy, history of alcohol consumption and patients in Current use of NSAIDs and corticosteroids.

Intervention groups

Prescribed drugs for both treatment and control groups: bismuth subcitrate 240 mg twice a day, amoxicillin 1 gram twice a day, metronidazole 500 mg twice a day, omeprazole 20 mg once a day for two weeks. In two groups, taking omeprazole will continue for one month. In the treatment group, beta-cyclodextrin and propolis complex 250 mg once a day, and in the control group, a placebo capsule containing starch with the same appearance as the beta-cyclodextrin propolis capsule is given daily for two months will be prescribed.

Main outcome variables

Improvement of digestive symptoms, eradication of *Helicobacter pylori*

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230503058065N1**

Registration date: **2024-01-22, 1402/11/02**

Registration timing: **prospective**

Last update: **2024-01-22, 1402/11/02**

Update count: **0**

Registration date

2024-01-22, 1402/11/02

Registrant information

Name

Aisa Mehri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3832 5546

Email address

aisaamehri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-04-17, 1403/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of cyclodextrin and propolis complex as adjuvant treatment in patients with Helicobacter pylori

Public title
Effect of propolis as an adjuvant treatment of Helicobacter pylori

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with symptoms of dyspepsia Helicobacter pylori patients with a positive biopsy test
Exclusion criteria:
 People with duodenal gastrointestinal bleeding Pregnant women Breastfeeding women Patients with liver disorders Patients with renal failure Patients with heart failure Patients with a history of drug sensitivity to any of the studied drugs Patients who have previously been treated with Helicobacter pylori therapy Patients taking NSAIDs Patients who are taking corticosteroids Patients with a history of alcohol consumption

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
 Eligible patients will be divided into two treatment and control groups by block randomization. The randomization sequence will be in the form of 25 blocks of 4 in which the number of treatments is equal in each block. Blocks will be numbered from one to 25. In a simple random method, using a table of random numbers of blocks, the selection and sequence of treatments in the block will be the basis for assigning patients to treatments. The block randomization sequence is extracted from the following website.
<https://www.sealedenvelope.com/simple-randomiser/v1/lists>

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient, physician and research student who are responsible for collecting information will not know about the allocation of patients to treatment groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences., Shahid Fahmide Blvd., Pazhohesh Square

City

Hamedan

Province

Hamadan

Postal code

6517768993

Approval date

2023-04-29, 1402/02/09

Ethics committee reference number

IR.UMSHA.REC.1402.088

Health conditions studied

1

Description of health condition studied

Helicobacter Pylori infection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improvement of digestive symptoms

Timepoint

60 days after the start of the intervention

Method of measurement

Questionnaire and fecal antigen test

Secondary outcomes

1

Description

Helicobacter pylori eradication

Timepoint

60 days after the start of the intervention

Method of measurement

Fecal antigen test

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Dr Alireza Khalilian

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No. 1, Eram Blvd., Ghaem Square

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2

Recruitment center

Name of recruitment center

Atiyeh hospital

Full name of responsible person

Dr Mahdi safari

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Imam Khomeini Street, Shahid madani settlement

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokouhi

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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

Aisa Mehri

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the privacy of participants' data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available