

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Oct 2026

Investigating the effectiveness of propolis as an adjuvant treatment for the eradication of *Helicobacter pylori*: Double-blind randomized controlled clinical trial

Protocol summary

Study aim

The effect of propolis on fecal *Helicobacter pylori* antigen and gastrointestinal symptoms in people with *Helicobacter pylori* infection.

Design

Randomized clinical trial

Settings and conduct

This study will be conducted on patients with *Helicobacter pylori* infection referred to gastroenterology clinics of Urmia University of Medical Sciences. The study participants will be assigned to one of the two propolis or placebo groups using simple randomization. The intervention period will be 14 days. The subjects in the first group will receive 300 mg capsules containing propolis supplement (containing 50 mg propolis extract) 2 times a day, and the subjects in the second group will also receive the same amount of placebo capsules. Only the person responsible for packing the capsules containing propolis and placebo will know the relevant codes, and none of the researchers or patients will know the type of capsule that each person receives. All patients will receive standard *Helicobacter pylori* treatment which includes antibiotics. Participants will record their daily symptoms in a standardized questionnaire at baseline and at the second and fourth week after treatment. *Helicobacter pylori* antigen test will be used to evaluate the eradication of *Helicobacter pylori* in 2 weeks after completion of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-60 years old *Helicobacter pylori* infected patients Exclusion criteria: Chronic diseases such as diabetes, CKD, Malignancy, gallbladder disorders, peptic ulcer and upper gastrointestinal surgery Consumption of propolis or other antioxidant supplements or herbal drugs over the past 3 months allergy to propolis

Intervention groups

Propolis and placebo

Main outcome variables

Anti-*Helicobacter pylori* antigen; *Helicobacter pylori* caused gastrointestinal complaints

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240622062210N1**

Registration date: **2024-08-01, 1403/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2024-08-01, 1403/05/11**

Update count: **0**

Registration date

2024-08-01, 1403/05/11

Registrant information

Name

Fatemeh Hajizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of propolis as an adjuvant treatment for the eradication of *Helicobacter pylori*:
Double-blind randomized controlled clinical trial

Public title
propolis supplementation for the eradication of
Helicobacter pylori

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18-60 years old *Helicobacter pylori* infected patients
Exclusion criteria:
Chronic diseases such as diabetes, CKD, Malignancy, gallbladder disorders, peptic ulcer and upper gastrointestinal surgery Consumption of propolis or other antioxidant supplements or herbal drugs over the past 3 months allergy to propolis

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of subjects in each study groups (supplement and placebo) will be done by "Random Allocation Software" using the block random allocation method (blocks of 4).

Blinding (investigator's opinion)
Double blinded

Blinding description
Allocation concealment will be used to reduce the selection bias error. All investigators, study participants, and the person responsible for data analysis will be blinded to the allocated groups. After obtaining the inclusion criteria, sealed envelopes with unique codes generated by Random Allocation Software will be allocated to the subjects. The codes along with groups A and B (supplement group and placebo indicators) will be generated at the beginning of the study by one of the collaborators of the project, who is not involved in clinical phases of the intervention and sampling. The

investigators will remain unaware of the concept of codes and groups until the end of the study. Only A and B codes are inserted on the envelopes to identify two separate groups. After allocating patients in group A or B, the envelope is opened and the code inside the envelope that contains 4 numbers (for example 5372) with no concept and completely random will be labeled on the supplement box. Patients are not classified based on the A or B code and the numbers inside the envelope are the criteria for classification, and these codes are only used for labeling medicine and placebo boxes.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in research of Imam Khomeini Medical Education Center, Urmia University of Medical
Street address
Emam Khomeini hospital, Ershad ave, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
571478334

Approval date
2024-01-31, 1402/11/11

Ethics committee reference number
IR.UMSU.HIMAM.REC.1402.169

Health conditions studied

1

Description of health condition studied
Patients with *Helicobacter pylori* infection

ICD-10 code
K31.89

ICD-10 code description
Other diseases of stomach and duodenum

Primary outcomes

1

Description
Fecal anti-*Helicobacter pylori* antigen

Timepoint
14 days

Method of measurement

Measuring fecal anti-Helicobacter pylori antigen using PCR method

2

Description

Helicobacter pylori caused gastrointestinal complaints

Timepoint

14 days

Method of measurement

Helicobacter pylori caused gastrointestinal complaints questionnaire scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Propolis/ Propolis group will receive 300 mg propolis capsules (containing 50 mg propolis extract) 2 times a day for 14 days.

Category

Treatment - Other

2

Description

Control group: placebo/ Placebo group will receive 300 mg capsules containing maltodextrin supplement twice a day for 14 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal clinics of Urmia University of Medical Sciences

Full name of responsible person

Mohammadreza Pashaei

Street address

Clinical Research Institute, Imam Khomeini Educational and Medical Center, Modarres Blvd, Ershad St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr Saber Gholizadeh

Street address

Research and Technology Vice-Chancellor, Urmia University of Medical Sciences, at the end of Jihad St., Urmia

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Mohammadreza Pashaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available