Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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+98 44 3234 3476

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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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Email
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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 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