Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Efficacy and Safety of Pistacia atlantica Gum Essential Oil in Helicobacter pylori Eradication in Peptic Ulcer Disease: A Randomized Controlled Trial

Protocol summary

Study aim

Evaluation of Helicobacter pylori eradication rates in patients receiving Pistacia atlantica gum essential oil versus placebo

Design

A phase III, double-blind, placebo-controlled, single-center, randomized clinical trial with two parallel arms, including 80 patients allocated in a 1:1 ratio to intervention (n=40) and control (n=40) groups.

Settings and conduct

Eligible patients attending the outpatient gastroenterology clinic at Imam Hossein hospital will be enrolled in the study and randomly assigned to either the intervention or control group using a random number table. After starting the Helicobacter pylori eradication regimen, patients will be followed up at multiple time points to monitor adherence to the treatment. The study will be conducted in a double-blind manner, with both patients and researchers unaware of group assignments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: peptic ulcer along with positive Helicobacter pylori histopathology Exclusion criteria: renal or hepatic failure, pregnancy and breastfeeding

Intervention groups

Intervention group: patients receiving omeprazole 20 mg twice daily, metronidazole 500 mg twice daily, amoxicillin 1 g twice daily, bismuth subcitrate 240 mg twice daily, and Jiragastrin 200 mcg twice daily for 2 weeks with an additional 6 weeks of omeprazole 20 mg twice daily. Control group: patients receiving the same standard eradicaion regimen along with Jiragastrin placebo twice daily for 2 weeks with an additional 6 weeks of omeprazole 20 mg twice daily. Jiragastrin capsules (Jiran Darou, Kurdistan) contain Pistachia atlantica gum essential oil and are standardized based on 200 mcg alpha-pinene as the active ingredient in each soft gelatin capsule.

Main outcome variables

Helicobacter pylori eradication rate (in percent)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121021011192N22**
Registration date: **2026-01-15, 1404/10/25**
Registration timing: **prospective**

Last update: **2026-01-15, 1404/10/25**
Update count: **0**

Registration date

2026-01-15, 1404/10/25

Registrant information

Name

Mohammad Abbasinazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-01-20, 1404/10/30

Expected recruitment end date

2026-10-22, 1405/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy and Safety of Pistacia atlantica Gum Essential Oil in Helicobacter pylori Eradication in Peptic Ulcer Disease: A Randomized Controlled Trial

Public title
Wild Pistachio in Helicobacter pylori Eradication

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Peptic ulcer confirmed through esophagogastroduodenoscopy (EGD) by a gastroenterology specialist Positive Helicobacter pylori histopathology

Exclusion criteria:
Renal or hepatic failure Pregnancy and breastfeeding

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization will be performed using simple randomization with an allocation ratio of 1:1. The unit of randomization will be the individual, and each eligible patient will be considered as an independent unit in the randomization process. The random sequence will be generated using a random number table obtained from the website www.stattrek.com. Accordingly, a random, non-duplicate sequence of numbers 1 to 80 (based on the sample size) will be generated, considering the first 40 random numbers as group A and the second 40 random numbers as group B. Each patient will be assigned a number according to the order of entry and based on whether that number is in group A or B of the random sequence, will receive a medication labeled as such. Of note, the patients and investigators will not be informed of the assigned group to the patients (the intervention or control group) and labelling the medications as A or B will be carried out by an independent individual who is not involved in the study. To prevent allocation bias, allocation concealment will be ensured by keeping the randomization list with the independent individual and by restricting access of the researchers and outcome assessors to the allocation sequence until each patient is definitively enrolled in the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both the patients and investigators are blinded to the treatment allocation. The drug and placebo are identical in dosage form and packaging, and are labeled as A or B by a laboratory technician who is not involved in the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Pharmacy, Nursing, and Midwifery, Shahid Beheshti University of Medical Sciences

Street address
No. 2660, School of Pharmacy, Niayesh junction, Valiasr street

City
Tehran

Province
Tehran

Postal code
1996835113

Approval date
2025-09-16, 1404/06/25

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1404.150

Health conditions studied

1

Description of health condition studied
Peptic ulcer due to Helicobacter pylori infection

ICD-10 code
K27

ICD-10 code description
Peptic ulcer, site unspecified

2

Description of health condition studied
Positive histopathological test for Helicobacter pylori infection

ICD-10 code
B96.81

ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Helicobacter pylori eradication status
Timepoint
2 weeks after completion of the 8-week medication regimen
Method of measurement
Helicobacter pylori stool antigen test

Secondary outcomes

1

Description
Occurrence rate of adverse drug reactions
Timepoint
At the end of week 2 of Helicobacter pylori eradication regimen
Method of measurement
Interview with the patients

Intervention groups

1

Description
Intervention group: patients receiving omeprazole 20 mg twice daily, metronidazole 500 mg twice daily, amoxicillin 1 g twice daily, bismuth subcitrate 240 mg twice daily, and Jiragastrin (Jiran Darou - Sanandaj, Kurdistan) 200 mcg twice daily for 2 weeks with an additional 6 weeks of omeprazole 20 mg twice daily. Jiragastrin capsules contain Pistachia atlantica gum essential oil and are standardized based on 200 mcg alpha-pinene as the active ingredient in each soft gelatin capsule.
Category
Treatment - Drugs

2

Description
Control group: patients receiving omeprazole 20 mg twice daily, metronidazole 500 mg twice daily, amoxicillin 1 g twice daily, bismuth subcitrate 240 mg twice daily, and Jiragastrin placebo (Jiran Darou - Sanandaj, Kurdistan) twice daily for 2 weeks with an additional 6 weeks of omeprazole 20 mg twice daily
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Medical and Educational Hospital
Full name of responsible person
Mohammad Abbasinazari
Street address
Imam Hossein medical and educational hospital, Shahid Madani street
City
Tehran
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Postal code
1617763141
Phone
+98 21 7343 3000
Email
info@sbmu.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, Arabi street, Daneshjoo boulevard, Velenjak
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Postal code
1985717443
Phone
+98 21 2371 0000
Email
zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammad Abbasinazari

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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Professor

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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
Undecided - It is not yet known if there will be 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
All data may potentially be shared after de-identification of individual participants.

When the data will become available and for how long
Starting in September 2028.

To whom data/document is available
Only available for people working in academic institutions.

Under which criteria data/document could be used
Researchers whose use of the data has been approved by an independent scientific committee should send an email to m_abbasi@sbmu.ac.ir, providing a written certificate for this purpose.

From where data/document is obtainable
Send email to: m_abbasi@sbmu.ac.ir.

What processes are involved for a request to access data/document
Requests can be submitted for up to 6 months after publication of the related article. A response will be emailed to the requester within a maximum of one month.

Comments