

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the phytochemical and clinical effect of herbal mixture of Pistacia Atlantica and Quercus Brantii versus placebo in Helicobacter pylori positive patients with gastritis and peptic ulcer: a triple-blind randomized clinical trial

Protocol summary

Study aim

To evaluate the phytochemical and clinical effect of herbal mixture of Pistacia Atlantica and Quercus Brantii versus placebo in Helicobacter pylori positive patients with gastritis and peptic ulcer

Design

This is a triple-blind randomized clinical trial, phase II, in which 78 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible Helicobacter pylori positive patients with gastritis and peptic ulcer who will refer to Shahid Beheshti Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 80 years; Gastritis or gastric ulcer; Positive urease test Exclusion criteria: Pregnancy or breastfeeding; Previous treatment of helicobacter pylori; Duodenal bleeding; Liver disorder; Renal failure; Heart failure; Using nonsteroidal anti-inflammatory drugs or corticosteroid and bismuth Using alcohol; Using antibiotic or antacid

Intervention groups

Intervention group: Standard triple-drug regiment for helicobacter pylori for 2 weeks plus one capsule including herbal mixture of Pistacia Atlantica and Quercus Brantii 500 mg/day for 2 weeks Control group: Standard triple-drug regiment for helicobacter pylori for 2 weeks plus one placebo capsule per day for 2 weeks

Main outcome variables

Primary outcome: Symptoms of gastritis and gastric ulcer Helicobacter pylori irradiation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N233**

Registration date: **2018-09-03, 1397/06/12**

Registration timing: **prospective**

Last update: **2018-09-03, 1397/06/12**

Update count: **0**

Registration date

2018-09-03, 1397/06/12

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the phytochemical and clinical effect of herbal mixture of Pistacia Atlantica and Quercus Brantii versus placebo in Helicobacter pylori positive patients with gastritis and peptic ulcer: a triple-blind randomized clinical trial

Public title

Evaluation of the phytochemical and clinical effect of herbal mixture of Pistacia Atlantica and Quercus Brantii versus placebo in Helicobacter pylori positive patients with gastritis and peptic ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 80 years; Gastritis or gastric ulcer; Positive urease test

Exclusion criteria:

Pregnancy or breastfeeding; Previous treatment of helicobacter pylori; Duodenal bleeding; Liver disorder; Renal failure; Heart failure; Using nonsteroidal anti-inflammatory drugs or corticosteroid and bismuth Using alcohol; Using antibiotic or antacid

Age

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

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions Therefore, the trial will be run as triple blind

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

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.UMSHA.REC.1397.303

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

Symptoms of gastritis and gastric ulcer

Timepoint

Before and 2 weeks and 3 months after intervention

Method of measurement

By history taking

2

Description

Helicobacter pylori irradiation

Timepoint

3 months after intervention

Method of measurement

By urease test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Standard triple-drug regiment for helicobacter pylori for 2 weeks plus one capsule including herbal mixture of Pistacia Atlantica and Quercus Brantii 500 mg/day for 2 weeks

Category

Treatment - Drugs

2

Description

Control group: Standard triple-drug regiment for helicobacter pylori for 2 weeks plus one placebo capsule per day for 2 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Arefeh Shojaeian

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School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Arefeh Shojaeian

Position

Pharmacology Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Dara Dastan

Position

Pharmacologist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

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