Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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
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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
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Person responsible for updating data

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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