Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the efficacy of hydroalcoholic extract of Iranian oak (germ and seed coat) with proton pump inhibitor (PPI) treatment in improving the symptoms of patients with gastroesophageal reflux

Protocol summary

Study aim

Comparing the efficacy of hydroalcoholic extract of Iranian oak (germ and seed coat) with proton pump inhibitor (PPI) treatment in improving the symptoms of patients with gastroesophageal reflux

Design

A randomized clinical trial with a control group, with parallel group design, double-blind, will be conducted on 90 patients. Randomization will be done through a block randomization method using blocks of size 4

Settings and conduct

This research is a randomized, double-blind controlled clinical trial that will be conducted on patients with gastroesophageal reflux disease (GERD) referred to the gastroenterology clinics of Imam Khomeini Hospital and Golestan Hospital in Ahvaz. To prevent bias until the end of the research, all members of the treatment and research team will be unaware of the codes (drug type) and after the end of the treatment, the codes will be opened

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients between 20 and 60 years old; diagnosed with gastroesophageal reflux (GERD) based on clinical symptoms (reflux at least twice a week) and diagnostic endoscopy (esophagogastroduodenoscopy) and according to the Los Angeles classification (grades A to D). Non-inclusion criteria: Patients who are infected with H. pylori in the initial diagnostic examinations and before the start of the intervention, based on stomach biopsy or stool test; presence of coagulation disorders or GI bleeding.

Intervention groups

Intervention group 1: There are patients who are treated with a medicinal product prepared from Iranian oak. Control group 1: As a positive control group, they will take pantoprazole. Control group 2: As a negative control group, they will take a placebo

Main outcome variables

Gastroesophageal reflux score in the health-related quality of life questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230304057615N1**
Registration date: **2023-07-02, 1402/04/11**
Registration timing: **prospective**

Last update: **2023-07-02, 1402/04/11**
Update count: **0**

Registration date

2023-07-02, 1402/04/11

Registrant information

Name

Amir Mohammad Zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2024-10-01, 1403/07/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the efficacy of hydroalcoholic extract of Iranian oak (germ and seed coat) with proton pump inhibitor (PPI) treatment in improving the symptoms of patients with gastroesophageal reflux

Public title
Evaluation of the effect of hydroalcoholic extract of oak in patients with gastroesophageal reflux disease (GERD)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are between 20 and 60 years old Diagnosed with gastroesophageal reflux (GERD) based on clinical symptoms (having reflux at least twice a week), diagnostic endoscopy (esophagogastroduodenoscopy) and the Los Angeles classification (grades A to D) Not taking PPI for at least 1 week before entering the study
Exclusion criteria:
Patients who are infected with H. pylori in the initial diagnostic examinations and before the intervention, based on stomach biopsy or stool test Patients with coagulation disorders or GI bleeding Patients who have a history of upper GI surgery or suffer from other digestive diseases such as irritable bowel syndrome, peptic ulcer, obstructive disease, etc Patients with Zollinger-Ellison syndrome, primary motility disorders, Barrett's esophagus, esophageal stricture, and any severe disease with reflux and malignancy of the upper gastrointestinal tract, as well as pregnant or lactating women Patients who take PPIs from 28 days before diagnostic endoscopy or H2 receptor antagonists from 14 days before diagnostic endoscopy Patients who take NSAIDs or other drugs that may interfere with the interpretation of the study result. (diazepam, quinidine, Dilantin, warfarin, anticholinergics, prostaglandin analogs, or sucralfate) Patients with chronic kidney, lung, and liver diseases and ... Patients who have a history of sensitivity to pantoprazole or seasonal allergies or asthma Patients who consume alcohol or drugs
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized using block randomization method and using blocks of size 4. And the patients are divided into three groups of 30 people and blocked randomization is for the purpose of making sure that exactly equal number of participants are included in the intervention and control groups in consecutive but equal time intervals
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo ingredients will be filled in capsules of the same color and similar to the original drug, and then the drug, placebo and pantoprazole capsules (pantoprazole 40 mg capsule produced by Dorsa Daru Company) will be coded by the pharmacist and to prevent bias, all members of the treatment and research team will be unaware of the codes until the end of the research, and after the end of the treatment, the codes will be opened.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz Jundi Shapur University of Medical Sciences
Street address
Jundishapur University of Medical Sciences., Esfand St., Golestan Blvd., Ahvaz
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Province
Khouzestan
Postal code
6135715794
Approval date
2023-03-12, 1401/12/21
Ethics committee reference number
IR.AJUMS.REC.1401.530

Health conditions studied

1

Description of health condition studied
Gastroesophageal reflux
ICD-10 code
K21.9
ICD-10 code description
Gastro-esophageal reflux disease without esophagitis

Primary outcomes

1

Description
Gastroesophageal reflux score in the health-related quality of life questionnaire
Timepoint
All patients are evaluated at the beginning of the study (before the intervention) and at the end of the first, second and fourth week
Method of measurement
Health-related quality of life questionnaire (related to GERD)

Secondary outcomes

1

Description
Gastroesophageal reflux score in frequency scale questionnaire for symptoms
Timepoint
All patients are evaluated at the beginning of the study (before the intervention) and at the end of the first, second and fourth week
Method of measurement
The frequency scale for the symptoms questionnaire

Intervention groups

1

Description
Intervention group :First, the oaks of the Quercus Persica species will be collected from the forests of the Zagros mountains in Mal Agha village, Baghmelk city, Khuzestan province, and a sample of them will be handed over to the pharmacognosy group to determine the genus and species and obtain the herbarium code. After that, the oaks are peeled and screened for quality, and then they are dried in a suitable environment at a temperature of 30 to 40 degrees and away from sunlight. After that, the dried oak fruits are crushed and ground by a grinder machine and sent to Ibn Masowayeh plant processing plant to produce hydroalcoholic extract, and in standard and hygienic conditions, the desired extract is prepared by spray drying. and then its tannin and polyphenol percentage will be determined. For the formulation of 200 mg capsules, which will be done in the pharmaceutical growth center under the supervision of a pharmaceutical specialist, first the powder is mixed with the permitted auxiliary substances such as Avicel and magnesium stearate homogeneously and uniformly by the Eruka machine, and then in empty capsules of zero size and They will be filled with Iran gelatin brand by filling machine. Finally, the capsules are controlled by weight and ready for using.Capsules prepared from oak fruit extract are prepared in doses of 200 mg and patients take the medicine for 1 month in two times, morning and evening.
Category
Treatment - Drugs

2

Description
Control group 1: There are patients who will take pantoprazole 40 mg for 1 month , daily and before eating breakfast.
Category
Treatment - Drugs

3

Description
Control group2: There are patients who will take a placebo for 1 month in two times, morning and evening.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Imam Khomeini Hospital
Full name of responsible person
Ali Akbar Shayesteh
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Ahvaz 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
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Ali Akbar Shayesteh
Position
Associate Professor
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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 more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available