

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of *Elaeagnus angustifolia* on reducing the symptoms of dyspepsia in comparison with placebo in patients with functional dyspepsia.

Protocol summary

Study aim

General aim: To determine the effect of the *Elaeagnus angustifolia* product on the severity of dyspepsia symptoms compared to placebo in patients with functional dyspepsia. Specific goals: Determining the average severity of dyspepsia symptoms in the placebo group before, 2 and 4 weeks after the intervention. Determining the average severity of dyspepsia symptoms in the group receiving the *Elaeagnus angustifolia* product before, 2 and 4 weeks after the intervention. Comparison of the average severity of dyspepsia symptoms in the above two groups before, 2 and 4 weeks after the intervention. Determining and comparing the average severity of dyspepsia symptoms in two groups before and after the intervention.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 98 patients.

Settings and conduct

This study will be conducted as a double-blind controlled clinical trial (patient and group evaluator, coding of drugs by the drug manufacturing company causes blinding) with two parallel wings. Patients referred to Khurshid Gastroenterology Clinic who are diagnosed with functional dyspepsia according to the Rome IV criteria are included in the study and *Elaeagnus angustifolia* product is prescribed to the patient.

Participants/inclusion and exclusion criteria

Inclusion: Patients referred to Khurshid Gastroenterology Clinic who are diagnosed with functional dyspepsia according to Rome IV criteria exclusion: Patient who have structural dyspepsia diseases (during endoscopic examination) or They have recently taken digestive medicines

Intervention groups

For the intervention group, one omeprazole 20 mg capsule per day, plus one tablet containing *Elaeagnus*

angustifolia product, three times after three meals, is prescribed for one month.

Main outcome variables

GSRS questionnaire (Gastrointestinal symptom rating scale)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221224056906N1**

Registration date: **2023-02-13, 1401/11/24**

Registration timing: **prospective**

Last update: **2023-02-13, 1401/11/24**

Update count: **0**

Registration date

2023-02-13, 1401/11/24

Registrant information

Name

Vahid Zarghami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5333 7848

Email address

vahid.z1395@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Elaeagnus angustifolia on reducing the symptoms of dyspepsia in comparison with placebo in patients with functional dyspepsia.

Public title

Effect of Elaeagnus angustifolia on dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients referred to Khurshid Gastroenterology Clinic who are diagnosed with functional dyspepsia according to Rome IV criteria

Exclusion criteria:

Patient who have structural dyspepsia diseases (during endoscopic examination) They have recently taken digestive medicines

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by block method. Blocks of 8 include 4 participants in the Elaeagnus angustifolia group and 4 participants in the placebo group. EPI-INFO-7 software is used for ease of work.

Blinding (investigator's opinion)

Double blinded

Blinding description

Coding of drugs by the drug manufacturing company causes blinding of the study from the side of the clinical supervisor and the researcher. In this way, the main drug (Elaeagnus angustifolia) , and the placebo are coded and decoded after evaluating the effects of the drug by the evaluator of the group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical committee of medical university of Isfahan

Street address

Hezar jarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-08-22, 1401/05/31

Ethics committee reference number

IR.ARI.MUI.REC.1401.155

Health conditions studied**1****Description of health condition studied**

Functional dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

Primary outcomes**1****Description**

Average range of dyspepsia symptoms

Timepoint

before the intervention and 2 weeks after and 4 weeks after the start of the drug

Method of measurement

GSRS questionnaire (Gastrointestinal symptom rating scale)

Secondary outcomes

empty

Intervention groups**1****Description**

intervention group : one omeprazole 20 mg capsule per day, plus one tablet containing Elaeagnus angustifolia product, three times after three meals, is prescribed for one month.

Category

Treatment - Drugs

2

Description

Control group: one omeprazole 20 mg capsule per day, plus one tablet of placebo, three times after three meals, is prescribed for one month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid hospital

Full name of responsible person

Maryam Soheilipour

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Hasht Behesht street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Gholamreza Asgari

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Soheilipour

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Digestive

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Ansaripour

Position

Non-faculty specialist doctor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional medicine

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vahid Zarghami

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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