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
Isfehan
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
Street address
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
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Position
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Person responsible for updating data

Contact

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Esfahan University of Medical Sciences

Full name of responsible person
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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