

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of the effect of the hydroalcoholic extract of the medicinal plant Xenian (Trachyspermum mammi L.), omeprazole and their simultaneous use on the symptoms and quality of life related to the health of patients with gastro-oesophageal reflux.

Protocol summary

Study aim

Determining Comparison of the effect of the hydroalcoholic extract of the medicinal plant Xenian (Trachyspermum mammi L.), omeprazole and their simultaneous use on the symptoms and quality of life related to the health of patients with gastro-oesophageal reflux.

Design

Clinical trial, with factorial groups, randomized, phase 3 on 120 patients

Settings and conduct

Approval of the research plan in the university ethics committee. At the beginning of the study, completion of the checklist of demographic characteristics, reflux symptom index questionnaire and Health-related quality of life - gastroesophageal reflux disease. Intervention in three groups of intervention 1 (Zenian essential oil capsules 150 mg), intervention 2 (Omeprazole capsules 20 mg) and intervention 3 (Zenian essential oil capsules 150 mg and Omeprazole capsules 20 mg at the same time), Once a day for 4 weeks. Immediately after finishing the interventions, re-completion of the reflux symptom index questionnaire and Health-related quality of life - gastroesophageal reflux disease. The place of the intervention is the gastroenterology clinic.

Participants/Inclusion and exclusion criteria

Admission requirements: 1- Age 18-60 2- Consent to participate in the study and sign the informed consent form. Conditions of non-entry: 1- Taking antibiotics or non-steroidal anti-inflammatory drugs 2 weeks before the study 2- Previous participation in studies similar to the current research.

Intervention groups

Intervention group 1: Zenian essential oil capsules 150 mg: They use it once a day for 4 weeks. Intervention group 2: Omeprazole capsules 20 mg: It will be used

once a day for 4 weeks. Intervention group 3: Zenian essential oil capsules 150 mg and Omeprazole capsules 20 mg at the same time: It will be used once a day for 4 weeks.

Main outcome variables

Improvement of gastroesophageal reflux symptoms and health-related quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220619055216N1**

Registration date: **2022-11-13, 1401/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-13, 1401/08/22**

Update count: **0**

Registration date

2022-11-13, 1401/08/22

Registrant information

Name

Alikaram Alamdari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of the hydroalcoholic extract of the medicinal plant Xenian (*Trachyspermum mammi* L.), omeprazole and their simultaneous use on the symptoms and quality of life related to the health of patients with gastro-oesophageal reflux.

Public title

Investigating the effect of herbal medicine *Trachyspermum mammi* L on the symptoms of gastro-oesophageal reflux

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being 18-60 years old
Consent to participate in the study and sign the informed consent form
Diagnosing gastroesophageal reflux by gastroenterologist based on ROME III criteria
Body mass index (BMI) less than 30 (BMI>30)
Absence of systemic diseases
Absence of neurological defects

Exclusion criteria:

Taking antibiotics or non-steroidal anti-inflammatory drugs 2 weeks before the study
Previous participation in studies similar to the current research
Drug or alcohol abuse
Existence of gastrointestinal malignancy based on history, physical examination, laboratory tests (for example, the number of white blood cells, CRP, ESR, and upper endoscopy)
Liver and kidney function disorders based on laboratory tests
Pregnancy
History of severe allergy to medicinal plants
History of upper gastrointestinal surgery and serious diseases such as heart failure, diabetes, epilepsy, previous or current significant psychiatric disorders

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Block random assignment will be done in such a way that according to the number of groups under study (three groups) including intervention 1 (Zenian essential oil capsules 150 mg), intervention 2 (Omeprazole capsules

20 mg) and intervention 3 (Zenian essential oil capsules 150 mg and Omeprazole capsules 20 mg at the same time) and calculated based on the factorial law, i.e. $3 = 1 \times 2 \times 6 = !3$, all the possible arrangements of the subjects considering A for the intervention group 1 (Zenian essential oil capsules 150 mg), B for the intervention group 2 (Omeprazole capsules 20 mg) and C for the intervention group 3 (Zenian essential oil capsules 150 mg and Omeprazole capsules 20 mg at the same time) will be compiled based on the following table: 1 2 3 4 5 6 CBA CAB BCA BAC ACB ABC Then, since the estimated sample size was 120 people, in each block, three samples, each representative of a study group and their arrangement order was also different, from these blocks, placement sampling will be done.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics Committee of Yasouj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

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7591741417

Approval date

2022-03-20, 1400/12/29

Ethics committee reference number

IR.YUMS.REC.1400.200

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

Patients with gastroesophageal reflux

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description

Reflux Symptom Index

Timepoint

Before and after the intervention

Method of measurement

reflux symptom index questionnaire

2

Description

Health-related quality of life - gastroesophageal reflux disease (GERD-HRQL)

Timepoint

Before and after the intervention

Method of measurement

Health-related quality of life - gastroesophageal reflux disease (GERD-HRQL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Zenian essential oil capsules 150 mg; They use it once a day for 4 weeks. Zenian essential oil is produced in Kashan essential oil Barich pharmaceutical company. In order to determine the safe dose and prepare herbal soft gel capsules according to the available sources, the maximum dose of essential oils studied in medicinal plants in humans for daily oral consumption for Zenian is equal to 500 mg. To prepare the ethanolic extract, the plant sample (Zenian seeds) was dried in the shade (room temperature) after collection. After it was ensured that the seeds were completely dried, they were powdered by a mill, then to prepare the ethanolic extract, 100 grams of the dried powder was mixed with 500 cc of 70% ethanol and kept for 48 hours at room temperature and in the dark (22 °C) is kept. Then, the obtained extract was filtered by filter paper and 70% alcohol solution was added to it again for another 24 hours and kept in the same conditions as before. After this time, it was filtered again by filter paper and the solution was put into a rotary evaporator at a speed of 100 revolutions per minute to remove alcohol, and finally the said solution was dried at 40 degrees Celsius in an incubator.

Category

Treatment - Drugs

2

Description

Intervention group 2: Omeprazole capsules 20 mg; It will be used once a day for 4 weeks.

Category

Treatment - Drugs

3

Description

Intervention group 3: Zenian essential oil capsules 150 mg and Omeprazole capsules 20 mg at the same time; It will be used once a day for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

مراجعه کنندگان به کلینیک های تخصصی شهر یاسوج

Full name of responsible person

Ehsan Elahinia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hossaini Motlagh

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

No

Title of funding source

Yasouj 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**

Yasouj University of Medical Sciences

Full name of responsible person

Ehsan Elahinia

Position

Master's student of medical sciences, Yasuj

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Other areas of specialty/work

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Other areas of specialty/work

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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