Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the effectiveness of a herbal product containing Rhus Coriaria L. (Sumac) and Pimpinella Anisum (Anise) in patients with Gastroesophageal Reflux compared to placebo: A double-blind Randomized Clinical Trial

Protocol summary

Study aim

Determining the effectiveness of a herbal product containing Sumac and Anise in patients with Gastroesophageal Reflux compared to placebo

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. Random Allocation software is used for randomization.

Settings and conduct

His research environment is the Colorectal Research Center of Iran University of Medical Sciences Medicine and placebo for blinding are given to patients in 500 mg capsules, so the patients participating in the study and the doctor do not know the type of control or intervention group. The medicine or placebo for each of the two groups is prescribed for 4 weeks. Then, in the 2nd and 4th week, the patient's condition is recorded by questionnaires. The sampling method is done as Balanced Block Randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have symptoms of reflux at least once a week and do not have complications in the field of reflux. People who have been diagnosed with reflux disease and have not taken medicine in the last 2 weeks and want to start anti-reflux treatment again. Exclusion criteria: Pregnancy and breastfeeding, the presence of signs and symptoms of danger.

Intervention groups

We put 3 grams of medicine (brown sumac and anise) as a mixture in a 500 mg capsule, and 2 pills are prescribed after each meal for 4 weeks. The placebo group was prescribed 500 mg of roasted bread flour in the same way. Reflux measures based on the clinical manual of reflux in Iranian medicine will be given to all patients participating in the project.

Main outcome variables

Severity and Frequency of Heartburn, Severity and Frequency Regurgitation; Stomach temperament; Drug Complications

General information

Reason for update

Acronym

GERD

IRCT registration information

IRCT registration number: **IRCT20231008059650N1**
Registration date: **2023-10-31, 1402/08/09**
Registration timing: **prospective**

Last update: **2023-10-31, 1402/08/09**
Update count: **0**

Registration date

2023-10-31, 1402/08/09

Registrant information

Name

Malihe zaman Momeniha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8856 1175

Email address

momeniha.mz@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of a herbal product containing Rhus Coriaria L. (Sumac) and Pimpinella Anisum (Anise) in patients with Gastroesophageal Reflux compared to placebo: A double-blind Randomized Clinical Trial

Public title

Evaluation of the effectiveness of a herbal product containing Rhus Coriaria L. (Sumac) and Pimpinella Anisum (Anise) in patients with Gastroesophageal Reflux compared to placebo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have gastroesophageal reflux symptoms at least once a week (Heartburn and Regurgitation) Patients who do not complication from gastroesophageal reflux disease. People who have been diagnosed with reflux disease and have not taken medicine in the last 2 weeks and want to start anti-reflux treatment again.

Exclusion criteria:

Patients with regular glucocorticoid intake Pregnancy Breastfeeding The presence of signs and symptoms of danger in the patient's history, such as weight loss of more than 10% during the last three months Patients with a history of Barrett's disease History of esophageal, stomach, or intestinal cancer Patients with coagulation disorders Patients with acute peptic ulcer or its complications

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the block randomization method and in this two-group clinical trial, we will have 4 blocks. For each person who enters the study, a code is obtained from the software and it is determined which group (intervention or control) it belongs to. We use specialized random Allocation concealment, this method is such that before the allocation of the individual, the allocated group is not known, in this way, by using non-transparent envelopes sealed with a random sequence, which in In this method, each of the random sequences created is recorded on a card and the cards are placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box. Blocking and preparation of envelopes is done by a person not involved in data sampling and analysis, in this way, the person who collects, the person who analyzes and the person who participates in the type of intervention received and what each person in They do not know about the placed group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients participating in the study and doctors or researchers do not know the type of control or intervention group.

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2023-10-07, 1402/07/15

Ethics committee reference number

IR.IUMS.REC.1402.601

Health conditions studied

1

Description of health condition studied

Gastroesophageal Reflux

ICD-10 code

K20-K31

ICD-10 code description

Diseases of oesophagus, stomach and duodenum

Primary outcomes

1

Description
Severity of heartburn based on (QOLRAD) (FSSG)
Timepoint
Severity of Heartburn before the start of the intervention, 2 and 4 weeks after the start of the intervention;
Method of measurement
Severity of Heartburn based on (FSSG) frequency scale for the symptoms of GERD و (QOLRAD) Quality Of Life in Reflux and Dyspepsia

2

Description
Frequency of Heartburn based on (QOLRAD) (FSSG)
Timepoint
Frequency of Heartburn before the intervention, 2 and 4 weeks after the intervention;
Method of measurement
Frequency of Heartburn based on (FSSG) frequency scale for the symptoms of GERD و (QOLRAD) Quality Of Life in Reflux and Dyspepsia

3

Description
Severity of Regurgitation based on (QOLRAD) (FSSG)
Timepoint
Severity of Regurgitation before the start of the intervention, 2 and 4 weeks after the start of the intervention;
Method of measurement
Severity of Regurgitation based on (FSSG) frequency scale for the symptoms of GERD و (QOLRAD) Quality Of Life in Reflux and Dyspepsia

4

Description
Frequency of Regurgitation based on (QOLRAD) (FSSG)
Timepoint
Frequency of Regurgitation before the intervention, 2 and 4 weeks after the intervention;
Method of measurement
Frequency of Regurgitation based on (FSSG) frequency scale for the symptoms of GERD و (QOLRAD) Quality Of Life in Reflux and Dyspepsia

Secondary outcomes

1

Description
Stomach temperament in terms of coldness, warmth, dryness and humidity
Timepoint
Before the start of the intervention and 4 weeks after the start of the intervention
Method of measurement
Stomach temperament questionnaires

2

Description
Drug side effects
Timepoint
Week 2 and 4 after the intervention
Method of measurement
Medication side effects questionnaire

Intervention groups

1

Description
Intervention group: In the medicine group, we put 3 grams of medicine (1.5 grams of brown sumac and 1.5 grams of anise) as a mixture, divided into 6 capsules of 500 mg and 2 tablets are prescribed after each meal for 4 weeks. The drug is made by professors specializing in Iranian medicine in the traditional pharmacy laboratory of the Faculty of Iranian Medicine, Iran University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: Toasted bread flour in 500 mg capsules is prescribed 2 times after each meal for 4 weeks. The medicine is made by professors specializing in Iranian medicine in the traditional pharmaceutical laboratory of the Faculty of Iranian Medicine, Iran University of Medical Sciences.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Colorectal Research Center of Iran University of Medical Sciences
Full name of responsible person
Shahram Agah
Street address
Building number one, 8th floor, Hazrat Rasool Akram (PBUH) Hospital, Niayesh Street., Sattar Khan Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Institute of Medical History, Islamic and Complementary Medicine Studies

Full name of responsible person
Amirhossein Jamshidi

Street address
Iran University of Medical Sciences., Hemmat highway

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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
Institute of Medical History, Islamic and Complementary Medicine Studies

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
Iran University of Medical Sciences

Full name of responsible person
Malihe zaman Momeniha

Position
Iranian Medicine Student

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Assistant Professor

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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
Not applicable

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available