

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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)

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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	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.
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	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.
Purpose Treatment	Placebo Used
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	Assignment Single Other design features Secondary Ids empty
Age From 20 years old to 60 years old Gender Both Phase 3 Groups that have been masked - Participant - Care provider - Investigator	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 ۱۴۳۹۶۱۴۵۳۵
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	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 , (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 , (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 , (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 , (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

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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

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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

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Latest degree

Medical doctor

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

Not applicable

Data Dictionary

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