

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Evaluation of the Effect of Traditional Herbal Products "Mastic & Coriander Triphala" on Gastroesophageal Reflux Disease in Adult Patients: A Randomized Double Blind Clinical Trial

Protocol summary

Study aim

The goal of this study is to provide herbal medicines with the least complications in controlling the symptoms of gastroesophageal reflux disease in adults 18 years of age and older in order to reduce the amount of drug use and minimize the side effects of the drugs. In this double-blind, randomized clinical trial, the effects of Mastic and Coriander Triphala on gastroesophageal reflux disease will be investigated.

Design

Participants in this study will be randomly divided in three parallel groups (two intervention groups and one control group) considering inclusion and exclusion criteria. In each block 52 participants will be studied through a double blind study.

Settings and conduct

18 year-old and above men and women with gastroesophageal reflux criteria who are referred to outpatient clinics of Shahid Madani, Sina and Imam Reza hospitals and endoscopic department of Shahid Madani and Imam Reza Hospitals in Tabriz city will be selected by unintended sampling method; and after obtaining written consent for participation in this research, they will be randomly divided to three groups (one control group and two intervention groups). The study is double blind. Drug and placebo instructions will be provided in the package. In all of the groups, a capsule in a small plastic will be taken before breakfast and the rest of the capsules will be consumed after a meal for 4 weeks. According to other studies, the sample size is 156 (52 participants in each intervention group and 52 participants in the control group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women 18 years old and older; Heartburn at least once a week; Return food from the stomach to the esophagus and mouth; Basic literacy (at least reading and writing skills); Exclusion criteria:

Taking anti-reflux medications; There are warning signs of weight loss, anemia, severe vomiting and food sting that have not been evaluated by endoscope; Barrett's esophagus; Esophagitis with non-reflux causes; Taking NSAID Drugs Pregnancy; Systemic diseases (liver disease, kidney disease, uncontrolled diabetes);

Intervention groups

Intervention group 1: In this group, patients will receive two Mastic capsules (each containing 500 mg of Mastic) three times a day for 4 weeks (Prepared from Tooba pharmacy -Ostad Nazem). Intervention group 2: In this group, patients will receive two Coriander Triphala capsules (each containing 500 mg of Coriander Triphala) three times a day for 4 weeks (Prepared from Tooba pharmacy -Ostad Nazem). Control group: In this group, patients will receive one Omeprazole capsule -20 mg- (packed in 500 mg capsule sachets) and 5 placebo capsules in a day.

Main outcome variables

The number of days the patient has heartburn (A burning feeling behind breastbone); The number of days the patient has regurgitation (stomach contents (liquid or food) moving upwards to throat or mouth); The number of days the patient has pain in the stomach (heartburn); The number of days the patient has nausea; The number of days the patient hasn't slept well due to heartburn or regurgitation; The number of days the patient uses other drugs in addition to previously prescribed medications due to heartburn or reflux; Quality of life; Duration of drug intake; Drug side effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180127038524N1**

Registration date: **2018-03-08, 1396/12/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-08, 1396/12/17**
Update count: **0**
Registration date
2018-03-08, 1396/12/17

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-20, 1396/12/01
Expected recruitment end date
2018-09-22, 1397/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Traditional Herbal Products "Mactic & Coriander Triphala" on Gastroesophageal Reflux Disease in Adult Patients: A Randomized Double Blind Clinical Trail

Public title
The effect of Mactic & Coriander Triphala Products on Gastroesophageal Reflux disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Men and women 18 years old and older Heartburn at least once a week Reflux from the stomach into the esophagus and mouth Basic literacy (at least reading and writing skills)
Exclusion criteria:
Taking anti-reflux medications warning signs including weight loss, anemia, severe vomiting and food sting in those who have not been evaluated by endoscope Barrett's esophagus Esophagitis with non-reflux causes Taking NSAID Drugs Pregnancy Systemic diseases (liver disease, kidney disease, uncontrolled diabetes

Age
From **18 years** old
Gender
Both
Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **156**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, randomization will be randomly done with fixed size blocks (blocks of size 4). The random numbers will be used to select blocks.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and researcher will be masked.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

No. 2. Central Building, Tabriz University of Medical Sciences, Gholghasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.TBZMED.REC.1396.968

Health conditions studied

1

Description of health condition studied

Gastroesophageal reflux disease

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description

The number of days the patient has heartburn (A burning feeling behind breastbone)

Timepoint

At the beginning of the study, 4 weeks during the intervention and 2 weeks after the end of the intervention.

Method of measurement

Frequency scale for the symptoms of gastroesophageal reflux disease questionnaire

Secondary outcomes

1

Description

The number of days the patient has regurgitation (stomach contents (liquid or food) moving upwards to throat or mouth).

Timepoint

At the beginning of the study, 4 weeks during the intervention and 2 weeks after the end of the intervention.

Method of measurement

FSSG (Frequency scale for the symptoms of gastroesophageal reflux disease).

2

Description

The number of days the patient has pain in the stomach (heartburn).

Timepoint

At the beginning of the study, 4 weeks during the intervention and 2 weeks after the end of the intervention.

Method of measurement

FSSG (Frequency scale for the symptoms of gastroesophageal reflux disease).

3

Description

The number of days the patient has nausea.

Timepoint

At the beginning of the study, 4 weeks during the intervention and 2 weeks after the end of the intervention.

Method of measurement

FSSG (Frequency scale for the symptoms of gastroesophageal reflux disease).

4

Description

The number of days the patient hasn't slept well due to heartburn or regurgitation.

Timepoint

At the beginning of the study, 4 weeks during the intervention and 2 weeks after the end of the intervention.

Method of measurement

FSSG (Frequency scale for the symptoms of gastroesophageal reflux disease).

5

Description

The number of days the patient uses other drugs in addition to previously prescribed medications due to heartburn or reflux.

Timepoint

At the beginning of the study, 4 weeks during the intervention and 2 weeks after the end of the intervention.

Method of measurement

FSSG (Frequency scale for the symptoms of gastroesophageal reflux disease).

6

Description

Quality of life

Timepoint

At the beginning of the study, 4 weeks during the intervention and 2 weeks after the end of the intervention.

Method of measurement

GERD_Quality of life questionnaire

7

Description

Duration of drug intaking

Timepoint

At the beginning of the study

Method of measurement

Interview

8

Description

Drug side effects

Timepoint

At the beginning of the study, 4 weeks during the intervention and 2 weeks after the end of the intervention.

Method of measurement

Interview

Intervention groups

1

Description

Intervention group 1: In this group, patients will receive two Mastic capsules (each containing 500 mg of Mastic) three times a day for 4 weeks (Prepared from Toba Pharmacy -Ostad Nazem).

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, patients will receive two Coriander Triphala capsules (each containing 500 mg of Coriander Triphala) three times a day for 4 weeks (Prepared from Toba Pharmacy -Ostad Nazem).

Category

Treatment - Drugs

3

Description

Control group: In this group, patients will receive one Omeprazole capsule -20 mg- (packed in 500 mg capsule sachets) and 5 placebo capsules a day, for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Seyed Mohammad Bagher Fazljoo

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Azadi Street

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Fariba Sadeghi

Position

Ph.D candidate of Traditional Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Seyed Mohammad Bagher Fazljoo

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Person responsible for updating data

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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

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