Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

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

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
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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 Gastroesophagal 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-re flux 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
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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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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
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Fariba Sadeghi
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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