

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of traditional medicine product based on Rosa damascena on gastroesophageal reflux disease (GERD): a double-blind clinical trial

Protocol summary

Study aim

The aim of this study was to determine the effect of traditional medicine product based on rose on gastroesophageal reflux disease (GERD).

Design

Controlled clinical trial with parallel groups. A randomized, double-blind, phase 3 study is performed on 70 patients.

Settings and conduct

Patients referred to the gastrointestinal clinic of Imam Hossein Hospital are randomly divided into two groups. Roses and placebo capsules for the same package and will be encrypted. Coding is done blindly. Placebo is used for medicinal corn starch. Patients in the drug group use rose capsules and placebo capsules. Both groups received Abaidi omeprazole capsules. In the beginning, after two weeks and in the fourth week, the patients have visited, and the reflux questionnaire is completed.

Participants/Inclusion and exclusion criteria

Patients with Gastro-Esophageal Reflux Disease aged 18 to 80 years. Exclusion criteria: having a history of Barrett's esophagus, history of esophageal or gastric surgery; History of esophageal, gastric, or abdominal cancer; Having coagulation problems that prevent them from stopping their medication.

Intervention groups

Intervention group: Rose capsule, this capsule is prepared in Tuba Green Gold Pharmaceutical Company. Patients take one rose capsule 3 times a day after each meal for 4 weeks. Control group: Placebo, this capsule is prepared in Tuba Green Gold Pharmaceutical Company. Patients take one capsule 3 times a day after each meal for 4 weeks.

Main outcome variables

Heartburn: Reflux throat: Pain in the middle and upper stomach :Nausea: Difficulty in falling asleep due to reflux symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200303046677N5**

Registration date: **2021-01-16, 1399/10/27**

Registration timing: **prospective**

Last update: **2021-01-16, 1399/10/27**

Update count: **0**

Registration date

2021-01-16, 1399/10/27

Registrant information

Name

rasool choopani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

rchoopani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of traditional medicine product based on Rosa damascena on gastroesophageal reflux disease (GERD): a double-blind clinical trial		blind).	
Public title	Effect of traditional medicine product based on Rosa damascena on gastroesophageal reflux disease (GERD)	Placebo	Used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria		Other design features	
Inclusion criteria:	With reflux at the age of 18 to 80 years	Secondary Ids	
Exclusion criteria:	Having a history of Barrett's esophagus History of esophageal, gastric or abdominal cancer Having coagulation problems that prevent them from stopping their medication Patients receiving regular glucocorticoids and nonsteroidal anti-inflammatory drugs more than three days a week for the past 28 days Receiving sucralfate three days before enrollment Take aspirin daily at a dose of more than 150 mg Acute peptic ulcer or its complications Receive antibiotic treatment to eradicate Helicobacter Pylori in the last 28 days Smoking or Alcohol	empty	
Age	From 18 years old to 80 years old	Ethics committees	
Gender	Both	1	
Phase	3	Ethics committee	
Groups that have been masked	- Participant - Care provider - Investigator	Name of ethics committee	
Sample size	Target sample size: 70	Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences	
Randomization (investigator's opinion)	Randomized	Street address	
Randomization description	A randomization table was created with the Excel software rand option. It was already clear that the process of reading random numbers was from top to bottom. Therefore, 35 random codes were assigned to the drug group and written on the drug, and the next 35 codes were written on the placebo, and the codes were kept confidential for use at the time of conclusion. The drugs were packed in the same containers, coded, and given to the researcher and the physician in an identical. Patients randomly received one of the containers of medication or placebo. Randomization unit: individual Randomization tool: Random number table	7th Floor, Bldg No.2 , Arabi Ave, Daneshjoo Blvd, Velenjak	
Blinding (investigator's opinion)	Double blinded	City	
Blinding description	Randomization is done by Excel software and by a researcher who has no involvement in the study. The codes are then written on the same container of medicine and placebo and will be kept confidentially in an envelope until the end of the study. The prescribing physician, assistant, And the patient will not be aware of the capsules' contents until the end of the study (double-	Tehran	
		Province	
		Tehran	
		Postal code	
		19839-63113	
		Approval date	
		2020-10-11, 1399/07/20	
		Ethics committee reference number	
		IR.SBMU.RETECH.REC.1399.602	
		Health conditions studied	
		1	
		Description of health condition studied	
		gastroesophageal reflux	
		ICD-10 code	
		K21	
		ICD-10 code description	
		Gastro-esophageal reflux disease	
		Primary outcomes	
		1	
		Description	
		Heartburn	
		Timepoint	
		On arrival, the second week and fourth week	
		Method of measurement	
		Questionnaire	
		2	
		Description	
		Reflux throat	
		Timepoint	
		On arrival, the second week and fourth week	
		Method of measurement	

Questionnaire

3

Description

Pain in the middle and upper stomach

Timepoint

On arrival, the second week and fourth week

Method of measurement

Questionnaire

4

Description

Nausea

Timepoint

On arrival, the second week and fourth week

Method of measurement

Questionnaire

5

Description

Difficulty in falling asleep due to reflux symptoms

Timepoint

On arrival, the second week and fourth week

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Placebo, this capsule is prepared in Tuba Green Gold Pharmaceutical Company and medicinal corn starch is used as a placebo, which is filled in capsules of the same color and size of the drug and packed in similar containers. Patients take one capsule 3 times a day after each meal for 4 weeks.

Category

Placebo

2

Description

Intervention group: Rose capsule, this capsule is prepared in Tuba Green Gold Pharmaceutical Company. It contains 10 units of rose (petals), 2 units of licorice (dry extract), valerian (root) and 1 part of turpentine (gum) each. The drug components are ground and filled in 500 mg capsules. Quality control of product components, microbial and fungal tests of components and the final product are performed based on valid pharmacopoeias. Patients take one rose capsule 3 times a day after each meal for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Clinic of Imam Hossein Hospital

Full name of responsible person

Habib Malekpour

Street address

Shahid Madani Ave - Imam Hossein Hospital

City

Tehran

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Tehran

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1617763141

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habib.malekpour@gmial.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somayeh Esmaeili

Street address

No.8, shams Ali, Valiasr Ave.

City

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1516745811

Phone

+98 21 8877 3521

Email

sesmaeili@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasool Choopani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Full name of responsible person

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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