Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Effect of rose oil (Rosa damascena) softgel on cardinal manifestations of patients with gastro-esophageal reflux disease in comparison with omeprazole capsule, a double blind randomized controlled trial

Protocol summary

Summary

The study is a randomized double blind controlled trial in which rose oil softgel is compared with omeprazole capsules on gastroesophageal reflux disease. The blinding is exerted for patients and researchers. Study population is the admitted outpatients to GI clinic of Rasoul Akram hospital. Each patient will be visited by a gastroenterologist and gastro-esophageal reflux disease (GERD) will be diagnosed clinically. Inclusion criteria include: Patients between 16 to 80 years old, patients have at least 12 weeks history of GERD, no inclusion of patients with peptic ulcer or its complications, no inclusion of patients taking antibiotics for H. pylori eradication during last 28 days. Exclusion criteria include: Appearance of drug adverse effects and loss of patient compliance. GERD patients fill the written consent form and conditions of the research will be explained. Then, the patients are randomly divided into two 35-patient groups: Group one: Rose oil softgel (two softgels TDS) + one placebo capsule (once daily). Group two: one 20 mg omeprazole capsule (once daily) + placebo softgel (two softgels TDS). Three visits are accomplished for each patient; First admission, 10 days later and 20 days later. The needed drug is rendered to the patients at the first admission for 10 days. At the 2nd visit, changes in the cardinal manifestations including heartburn and regurgitation will be evaluated. Then, the rest of drugs will be rendered. At the third visit changes will be evaluated again. Then, data gathering and analysis with SPSS will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101119489N1**
Registration date: **2016-06-11, 1395/03/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-11, 1395/03/22

Registrant information

Name

Meysam Shirzad

Name of organization / entity

School of traditional medicine, Tehran university of medical sciences

Country

Iran (Islamic Republic of)

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+98 21 8897 4535

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Recruitment status

Recruitment complete

Funding source

All funding comes from Barij Essence Pharmaceutical Company

Expected recruitment start date

2015-12-26, 1394/10/05

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of rose oil (Rosa damascena) softgel on cardinal

manifestations of patients with gastro-esophageal reflux disease in comparison with omeprazole capsule, a double blind randomized controlled trial

Public title
Effect of Rose oil on Gastro-esophageal Reflux Disease in comparison with omeprazole capsule
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients between 16 to 80 years old; Patients have at least 12 weeks history of GERD; No history of barrett's esophagus; No history of surgery on esophagus or stomach; No history of any cancer in esophagus, stomach or abdomen; No coagulation problem unable to withdrawal of drugs; No use of glucocorticoids and NSAIDs more than 3 days a week during last 28 days; No sucralfate use during 3 days before study; No aspirin use more than 150 mg daily; No active peptic ulcer or its complications; No antibiotic use for H. pylori eradication during last 28 days; No Cigarette smoking or alcohol drinking; Absence of any GERD complication. Exclusion criteria: Appearance of drug adverse effects; Loss of patient compliance
Age
From **16 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: Table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Qods St, Keshvarz Blv., Tehran, Iran
City
Tehran
Postal code
Approval date
2015-12-26, 1394/10/05
Ethics committee reference number
IR.TUMS.REC.1394.1485

Health conditions studied

1

Description of health condition studied
Gastro-esophageal reflux disease
ICD-10 code
k21
ICD-10 code description
Gastro-oesophageal reflux disease

Primary outcomes

1

Description
Numbers of regurgitation episodes
Timepoint
Onset of intervention and 10 and 20 days later
Method of measurement
History taking

2

Description
Numbers of heartburn episodes
Timepoint
Onset of intervention and 10 and 20 days later
Method of measurement
History taking

3

Description
Severity of regurgitations
Timepoint
Onset of intervention and twice 10 and 20 days later
Method of measurement
History taking

4

Description
Severity of heartburns
Timepoint
Onset of intervention and 10 and 20 days later
Method of measurement
History taking

Secondary outcomes

1

Description
age

Timepoint
at the beginning of the survey
Method of measurement
ID information

2

Description
sex
Timepoint
at the beginning of the survey
Method of measurement
inspection

3

Description
Duration of drug use
Timepoint
In 10 days intervals
Method of measurement
Patient statements

4

Description
Side effects
Timepoint
Twice in 10-day intervals
Method of measurement
History and physical exams

Intervention groups

1

Description
Intervention group: Rose oil softgel- two softgels TDS orally + one placebo capsule (once daily). Duration of consumption: 20 days - Rose oil softgel is manufactured by Barij Essence Co. - Placebo capsule is manufactured by Barij Essence Co.
Category
Treatment - Drugs

2

Description
Intervention group2 (Control group): One 20 mg omeprazole capsule (once daily) + placebo softgel (two softgels TDS). Duration of consumption: 20 days - omeprazole capsule is manufactured by Dr. Abidi Lab. - placebo softgel is manufactured by Barij Essence Co.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram general hospital
Full name of responsible person
Narjes Gorji, MD
Street address
Niayesh Ave., Sattarkhan St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences, Vice chancellor for research and technology
Full name of responsible person
Dr Masud Younesian
Street address
Tehran University of Medical Sciences, Vice chancellor for research and technology, 6th floor, corner of Qods Ave., Keshavarz Blvd.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences, Vice chancellor for research and technology
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Barij Essence Pharmaceutical Co.
Full name of responsible person
Mohammad Mahdi Ahmadian-Attari Pharm D
Position
Researcher
Other areas of specialty/work
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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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty