

# 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)

###### Phone

+98 21 8897 4535

###### Email address

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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****Street address**

No.132- Marzdaran St.

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Meysam Shirzad

**Position**

MD, PhD, Assistant professor- specialist in traditional medicine

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Tehran University of Medical Sciences

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Assistant professor- specialist in traditional medicine

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**Web page address****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*