

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Double blind randomized clinical trial in treatment of gastroesophageal reflux disease with *Myrtus Communis L.* (Myrtle) fruit vs. omeprazole

#### Protocol summary

##### Summary

The main purpose of this study is to compare the effect of *Myrtus Communis L.* (Myrtle) fruit with the standard treatment of Gastroesophageal reflux disease (GERD). Design: Double blind randomized clinical trial. This study is done on the 43 patients (18 to 50 years old) that have classic symptoms of GERD (heart burn that sometimes get better after eating food or anti acid drugs, sour taste in the mouth, feeling heavy after or before meal, feeling full while eating food,...). For all of the patients upper gastroesophageal endoscopy is done. The patients with ulcer in esophagus or stomach are excluded. The patients are divided in three groups randomly. The first group receive *Myrtus Communis L.* (Myrtle) fruit ( one capsule twice a day for 4 weeks), the second group receive Omeprazole( one capsule once a day for 4 weeks) and the third group receive *Myrtus Communis L.* (Myrtle) fruit ( one capsule twice a day for 4 weeks) with Omeprazole (one capsule once a day for 4 weeks). The patients are visited before and after treatment and their symptoms are scored according the VAS system and the frequency scale for the symptoms of gastroesophageal reflux questionnaire. Finally all groups will be compared according to their score.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012072710410N1**  
Registration date: **2013-02-10, 1391/11/22**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-02-10, 1391/11/22

#### Registrant information

##### Name

Rahimeh Akrami

##### Name of organization / entity

Shiraz University of Medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1233 7589

##### Email address

akrami@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research of Shiraz University of Medical Sciences

#### Expected recruitment start date

2012-07-22, 1391/05/01

#### Expected recruitment end date

2012-10-22, 1391/08/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Double blind randomized clinical trial in treatment of gastroesophageal reflux disease with *Myrtus Communis L.* (Myrtle) fruit vs. omeprazole

#### Public title

Assessment the Effect of *Myrtus Communis L.* (Myrtle) fruit in treatment of gastroesophageal reflux disease

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: having the classic symptoms of reflux; patients with 18-50 years old. Exclusion criteria: suffering

from another disease; ongoing alcohol users; weakly cooperative patients; pregnant women; breast feeding women; women in fertility ages without any contraceptive method; diabetic patients; erosive GERD; smoker patients.

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **43**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

**Street address**

Zand street

**City**

Shiraz

**Postal code**

197871345

**Approval date**

2012-01-21, 1390/11/01

**Ethics committee reference number**

5900-90-CT

**Health conditions studied****1****Description of health condition studied**

gastroesophageal reflux

**ICD-10 code**

K21.9

**ICD-10 code description**

gastroesophageal reflux without esophagitis

**Primary outcomes****1****Description**

reflux symptoms

**Timepoint**

before intervention and four weeks after starting the intervention

**Method of measurement**

visual analogue scale , frequency scale for symptoms of gastroesophageal reflux disease

**Secondary outcomes****1****Description**

headache after reflux

**Timepoint**

before intervention and four weeks after intervention

**Method of measurement**

according Statements

**Intervention groups****1****Description**

Control group: omeprazole capsule (once a day before breakfast)

**Category**

Treatment - Drugs

**2****Description**

Case group1: Myrtus Communis L. (Myrtle) fruit capsule (twice a day, before breakfast and dinner).

**Category**

Treatment - Drugs

**3****Description**

Case group2: Myrtus Communis L. (Myrtle) fruit capsule (twice a day, before breakfast and dinner) + omeprazole capsule (once a day before breakfast).

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Motahari Clinic

**Full name of responsible person**

Dr. Kazem Hosseini Asl

**Street address**

Zand street, Namazi square

**City**  
Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research of Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Hatam

**Street address**

Zand Street

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research of Shiraz University of Medical Sciences

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Rahimeh Akrami

**Position**

MD, Tadtional Medicine Resident

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Traditional medicine research center of Shiraz university of medical sciences

**Full name of responsible person**

Dr. Kazem Hosseini Asl, GI man

**Position**

Gastroentrolgist

**Other areas of specialty/work**

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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*