

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

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Name of organization / entity

Shiraz University of Medical sciences

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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

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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

Other areas of specialty/work

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Traditional medicine research center of Shiraz university of medical sciences

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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