Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 C ommunis 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 C ommunis 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 C ommunis 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 intenvention 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, Taditional Medicine Resident
Other areas of specialty/work
Street address
Zand Street
City
Shiraz
Postal code
713451978
Phone
+98 71 1230 5410
Fax
Email
akrami@sums.ac.ir
Web page address

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
Gastroentrologist
Other areas of specialty/work
Street address
Zand Street
City
Shiraz
Postal code
713451978
Phone
+98 71 1230 5410
Fax
+98 71 1647 4316
Email
hoseiniasl@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Rahimeh Akrami
Position
MD, Taditional Medicine Resident
Other areas of specialty/work
Street address
Zand Street
City
Shiraz
Postal code
713451978
Phone
+98 71 1230 5410
Fax
+98 71 1233 8476
Email
akrami@sums.ac.ir
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