

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation the effect of Myrtus Communis L. (Myrtle) fruit syrup, Traditional Iranian Medicine compound, on relapsing of Gastro esophageal reflux disease in patients 20 to 60 years old: a double blinded randomized controlled trial.

Protocol summary

Summary

Purpose: Evaluation the effect of Myrtus Communis L. (Myrtle) fruit syrup on relapsing of Gastro esophageal reflux disease. Design: Randomized, double blind, placebo controlled, and multicentral. Population: Cases were selected from Traditional Clinics and Shariati Hospital. Inclusion criteria: Age between 20-60 years, reflux symptoms more than once a week. Exclusion criteria: Alarm signs, having severe complication, sensitivity to Myrtus Communis. Study size: Ninety, after selecting the patients and taking inform consent, were randomized into 2 groups, using random number tables. Intervention: Case group: Myrtus Communis L. (Myrtle) fruit syrup, 5 cc after each meal, Breakfast and Lunch and Dinner, and Omeprazole capsule 20mg with fasting, for 6 Weeks. Control group: Placebo syrup of Myrtle fruit, 5 cc after each meal, Breakfast and Lunch and Dinner and Omeprazole capsule 20mg with fasting, for 6 Weeks. After this time, the drug has been discontinued and relapsing symptoms after 2 weeks will be reviewed. Main outcome variable is relapsing of Gastro esophageal reflux disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102719705N1**

Registration date: **2015-05-10, 1394/02/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-10, 1394/02/20

Registrant information

Name

Mehdi Salehi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3331 8165

Email address

m_salehi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-01-05, 1393/10/15

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Myrtus Communis L. (Myrtle) fruit syrup, Traditional Iranian Medicine compound, on relapsing of Gastro esophageal reflux disease in patients 20 to 60 years old: a double blinded randomized controlled trial.

Public title

Effect of Myrtus Communis in Gastro esophageal reflux disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with 20-60 years old; having reflux symptoms more than once a week. Exclusion criteria: Liver failure; cancer; pregnant women; surgery on stomach or esophagus; significant weight loss in 3 last months; melena or hematemesis; IBD; using PPI in the past 1 month; frequent using of NSAIDs.; severe chest pain; BMI>40; unwillingness to cooperation in study; sever complication; sensitivity to Myrtus Communis

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., Tehran, Iran

City

Tehran

Postal code

Approval date

2014-11-09, 1393/08/18

Ethics committee reference number

9021309003-126388

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

Relapsing of Gastro esophageal reflux

Timepoint

At first, end of the sixth week, end of the eighth week

Method of measurement

Gastro esophageal reflux standard questionnaire

Secondary outcomes

1

Description

Heartburn

Timepoint

At first, end of the sixth week, end of the eighth week

Method of measurement

Gastro esophageal reflux standard questionnaire

2

Description

Acid regurgitation

Timepoint

At first, end of the sixth week, end of the eighth week

Method of measurement

Gastro esophageal reflux standard questionnaire

3

Description

Chestpain

Timepoint

At first, end of the sixth week, end of the eighth week

Method of measurement

Gastroesophageal reflux standard questionnaire

4

Description

Dysphagia

Timepoint

At first, end of the sixth week, end of the eighth week

Method of measurement

Gastroesophageal reflux standard questionnaire

Intervention groups

1

Description

Case group: Oral syrup of Myrtus Communis L. (Myrtle) fruit, 5 cc after each meal, Breakfast and Lunch and Dinner, and Omeprazole capsule 20mg with fasting, for 6

Weeks Myrtus Communis L. (Myrtle) fruit syrup contains 1 gr of Myrtle fruit extract in 5 cc syrup. Base of the syrup is water and sugar.

Category

Treatment - Drugs

2**Description**

Control group: Placebo syrup of Myrtus Communis L. (Myrtle) fruit, 5 cc after each meal, Breakfast and Lunch and Dinner, and Omeprazole capsule 20mg with fasting, for 6 Weeks Intervention time is 6 Weeks for both groups and 2 Weeks after this time relapsing symptoms will be checked.

Category

Treatment - Drugs

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

Shariati Hospital

Full name of responsible person

Dr. Mehdi Salehi

Street address

Shariati Hosp, North Karegar Ave., Tehran, IRAN

City

Tehran

2**Recruitment center****Name of recruitment center**

Traditional Medicine Clinic

Full name of responsible person

Dr. Mehdi Salehi

Street address

Faculty of Traditional Medicine, Corner of Behesht St., Vahdat Eslami Ave., Tehran, IRAN

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Roja Rahimi

Street address

Faculty of Traditional Medicine, Corner of Behesht St., Vahdat Eslami Ave., Tehran, IRAN

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

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**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mehdi Salehi

Position

MD and PhD Student in Traditional Medicine

Other areas of specialty/work**Street address**

Faculty of Traditional Medicine, Corner of Behesht St., Vahdat Eslami Ave., Tehran, IRAN

City

Tehran

Postal code**Phone**

+98 21 3331 8165

Fax

+98 21 5560 1274

Email

m_salehi@razi.tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mehrdad Karimi

Position

Traditional Medicine Specialist

Other areas of specialty/work**Street address**

Faculty of Traditional Medicine, Corner of Behesht St., Vahdat Eslami Ave., Tehran, IRAN

City

Tehran

Postal code**Phone**

+98 21 5560 1274

Fax

+98 21 5560 1274

Email

mehrdadkarimi@yahoo.com

Web page address

+98 21 5560 1274

Email

m_salehi@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mehdi Salehi

Position

MD and PhD Student in Traditional Medicine

Other areas of specialty/work

Street address

Faculty of Traditional Medicine, Corner of Behesht St.,
Vahdat Eslami Ave., Tehran, IRAN

City

Tehran

Postal code

Phone

+98 21 3331 8165

Fax

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