Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Phyllanthus amblica (a Iranian traditional formula) in Non-erosive reflux disease

Protocol summary

Summary

The main purpose of this study is assessment of effects of phyllanthus amblica in non-erosive reflux disease (NERD). Design: Double blind randomized clinical trial. This study is done on the 68 patients (16 to 80 years old) that have classic symptoms of NERD (heart burn, sour taste in the mouth, feeling heavy after or before meal,...) and normal endoscopy. All patients are examined by a gastroenterologist. Patients with risk of peptic ulcer or malignancy, as well as pregnant and breast feeding women are excluded. The patients are divided in two groups randomly. The first group receive phyllanthus amblica tablets (two tablets two times a day for 4 weeks), the second group receive placebo tablets (two tablets two times a day for 4 weeks). phyllanthus amblica tablets and placebo produced in Faculty of Pharmacy Tehran University of Medical Sciences. The patients are visited before and after 2 and 4 weeks treatment and their symptoms are scored according the VAS system and the frequency scale for the symptoms of gastroesophageal reflux questionnaire (FSSG). Finally both groups will be compared according to their score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061428469N1**
Registration date: **2017-06-27, 1396/04/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-27, 1396/04/06

Registrant information

Name

Shahnaz Karkonvarnosfaderani

Name of organization / entity

School of Traditional Medicine, Tehran University of Medical Sciences (TUMS)

Country

Iran (Islamic Republic of)

Phone

+98 21 7789 6093

Email address

sh-karkon@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,School of Traditional Medicine, Tehran University of Medical Sciences

Expected recruitment start date

2016-07-11, 1395/04/21

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Phyllanthus amblica (a Iranian traditional formula) in Non-erosive reflux disease

Public title

Effects of Phyllanthus amblica in Non-erosive reflux disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having the classic symptoms of reflux disease and normal endoscopy; patients with 16 to 80 years old; the normal examination by a gastroenterologist Exclusion criteria: erosive esophagitis

in endoscopy; smoking; ongoing alcohol users; OB positive; risk of peptic ulcer or cancer; pregnant women; breast feeding women; any digestive disorder which requires new protocols; significant surgical or medical disorders clinically; hospitalization; use of PPI for 10 days ago; and use of H2 blocker for 2 weeks ago.

Age

From **16 years** old to **83 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The patients with classic symptoms of NERD (heart burn, sour taste in the mouth) and normal endoscopy that are examined by a gastroenterologist. The patients are given anti reflux diet for two weeks. The patients that did not better, are divided in two groups randomly. The first group receive phyllanthus amblica tablets, the second group receive placebo tablets. phyllanthus amblica tablets and placebo produced in Faculty of Pharmacy Tehran University of Medical Sciences. The patients are visited before and after 2 and 4 weeks treatment and their symptoms are noted.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

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

City

Tehran

Postal code

Approval date

2015-07-12, 1394/04/21

Ethics committee reference number

IR.TUMS.REC.1394.365

Health conditions studied

1

Description of health condition studied

Non-erosive gastroesophageal reflux disease (NERD)

ICD-10 code

K21.9

ICD-10 code description

Gastroesophageal reflux disease without esophagitis

Primary outcomes

1

Description

Pain or heartburn

Timepoint

At the begining, end of the Second week, end of the forth week

Method of measurement

Gastroesophageal reflux standard questionnaire

Secondary outcomes

1

Description

Acid regurgitasion /sour taste in the mouth

Timepoint

At the begining, end of the Second week, end of the forth week

Method of measurement

Gastroesophageal reflux standard questionnaire

Intervention groups

1

Description

Intervention group:Phyllanthus amblica tablet (two 500 mg tablets, two times a day for 4 weeks, after lunch and dinner)

Category

Treatment - Drugs

2

Description

Control group: placebo tablet (two 500 mg tablets, two times a day for 4 weeks, after lunch and dinner)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeiny Hospital

Full name of responsible person
Dr.Mohsen Nasiri Tosi/ Shahnaz Karkon Varnosfaderani
Street address
Qarib street
City
Tehran

2

Recruitment center
Name of recruitment center
Khark Traditional Medicine Clinic
Full name of responsible person
Shahnaz Karkon Varnosfaderani
Street address
Khark Street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,School of Traditional Medicine, Tehran University of Medical Sciences
Full name of responsible person
Dr. Roja Rahimi
Street address
School of Traditional Medicine, Tehran University of Medical Sciences, sarparast st, Taleqani st, Tehran
City
Tehran
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,School of Traditional Medicine, 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
School of Traditional Medicine, Tehran University of Medical Sciences (TUMS)
Full name of responsible person
Shahnaz Karkon Varnosfaderani
Position
MD, PhD candidate in Traditional Medicine
Other areas of specialty/work
Street address
School of Traditional Medicine, Tehran University of Medical Sciences, Sarparast st, Taleqani st.
City
Tehran
Postal code
Phone
+98 21 8899 3656
Fax
Email
sh.karkon@gmail.com; sh-karkon@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.Mohsen Nasiri Tosi
Position
Gastroenterologist/ Associate Professor
Other areas of specialty/work
Street address
Imam Khomeiny Hospital, Qarib st, Tehran
City
Tehran
Postal code
Phone
00
Fax
Email
mohsen_nasiri@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
School of Traditional Medicine, Tehran University of Medical Sciences (TUMS)
Full name of responsible person
Shahnaz Karkon Varnosfaderani
Position
MD, PhD candidate in Traditional Medicine
Other areas of specialty/work
Street address
School of Traditional Medicine, Tehran University of Medical Science, sarparast st, Taleqani st, Tehran
City
Tehran
Postal code
Phone
+98 21 7789 6093
Fax

Email
sh.karkon@gmail.com; sh-karkon@razi.tums.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