

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Effect of 10% extract syrup prepared from *Crataegus oxycantha* versus placebo on gastroesophageal reflux disease (GERD) symptoms

Protocol summary

Summary

The aim of the project is to prepare a herbal medicine with minimal side effects in controlling reflux symptoms so as to lessen the consumption of chemical drugs and to minimize the side effects thereof. The project is randomized, double-blind, placebo-controlled, and multi-center. People of 20-60 years old whose disease has recently been diagnosed or those who have not received medications during the past 2 months are enrolled in the study, provided that reflux symptoms (heartburn or regurgitation) would occur at least twice a week. People with high levels of creatinine and urea and/or liver enzymes are not enrolled. Those patients who take nonsteroidal anti-inflammatory drugs (NSAIDs), Digoxin, Cisapride, anti-arrhythmic and antiplatelet drugs are not entered in the study. A total of 80 patients are divided into two 40-member groups. The medicine is 10% extract syrup of *Crataegus oxycantha* prepared according to the United State Pharmacopia (USP) formulation. Preparation of the placebo is also based on the same formulation—but without the extract syrup of *Crataegus oxycantha*. One group is treated with the herbal medicine and the other with the placebo. Subsequent to each meal 5 ml of the syrup, either herbal medicine or placebo, should be taken by the participants of both groups. At the end of the 2nd and 4th weeks the symptoms (heartburn and regurgitation) are assessed and the results are compared across the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081314345N1**

Registration date: **2013-12-25, 1392/10/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-25, 1392/10/04

Registrant information

Name

Fatemeh Moini

Name of organization / entity

School of Traditional Medicine, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 10% extract syrup prepared from *Crataegus oxycantha* versus placebo on gastroesophageal reflux disease (GERD) symptoms

Public title

Effect of *Crataegus oxycantha* on gastroesophageal reflux disease (GERD) symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with reflux symptoms (heartburn or regurgitation) occurring at least 2 days a week; patients with uncomplicated reflux; newly diagnosed patients or diagnosed patients who have not used any drugs within the past 2 months. Exclusion criteria: Patients with high urea and creatinine levels; patients with elevated liver enzymes; patients who need to use nonsteroidal anti-inflammatory drugs (NSAIDs) daily; patients who use cardiac glycosides (Digoxin), antiarrhythmic drugs, antiplatelet drugs or Cisapride.

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: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The project is a double-blind study wherein both the medicine and the placebo are poured in identical containers coded by a pharmacist to be provided for the researcher. Neither is the researcher aware of the contents of each container nor do the patients know if they have taken medicine or placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Institute of Islamic and Complementary Medicine, Iran University of Medical Sciences

Street address

Pirnia Alley, Lalehzar Street, Jomhoori Street

City

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Postal code

Approval date

2013-05-23, 1392/03/02

Ethics committee reference number

113/پ26/م ط

Health conditions studied

1

Description of health condition studied

Gastroesophageal Reflux Disease

ICD-10 code

k21.9

ICD-10 code description

Gastro-oesophageal reflux disease without oesophagitis

Primary outcomes

1

Description

Heartburn, Regurgitation

Timepoint

At first, end of the second week, end of the forth week

Method of measurement

Clinical; how many days a week a patient suffers from the symptoms

Secondary outcomes

1

Description

Dysphagy, Chest Pain and Cough

Timepoint

At first, end of the second week, end of the forth week

Method of measurement

Clinical; how many days a week a patient has the symptoms

Intervention groups

1

Description

The patients in case group are treated with the drug (10% extract syrup of *Crataegus oxyantha*); they should drink 5 ml of the medicine after meal for 4 weeks.

Category

Treatment - Drugs

2

Description

The patients in control group are treated with the placebo and they should take 5 ml of the placebo after meal for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastrointestinal Clinic of Imam Khomeiny and Hazrat
Rasoul Hospitals

Full name of responsible person

Fatemeh Moini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Traditional Medicine, Tehran University of
Medical Sciences

Full name of responsible person

Ms. Talaee Zadeh

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Traditional Medicine College, Behesht Street, Hafez
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

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
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Full name of responsible person

Fatemeh Moini

Position

Physician, PhD student

Other areas of specialty/work

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Person responsible for scientific inquiries

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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