

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparable efficacy anise and corn starch in controlling symptoms in patients with Postprandial Distress Syndrome

Protocol summary

Summary

This study is designed to evaluate the efficacy of Pimpinella Anise product for patients with functional dyspepsia. Functional dyspepsia is characterized by a high prevalence rate and no standard conventional treatments which causes a significant reduction in the quality of life. Alternative therapies, such as herbal formulas, are widely used to treat FD. This randomized, double-blind, placebo-controlled trial will be performed at one University center and will include Pimpinella Anise product and placebo (corn) group. Each group will consist of 50 FD patients. four weeks of administration of Pimpinella Anise or placebo will be conducted. During the subsequent 2 months, follow-up observations of primary and secondary outcomes will be performed. The primary outcomes are differences as measured on the gastrointestinal symptoms scale and the secondary outcomes are differences as measured on the visual analogue scale for dyspepsia and on the questionnaire for FD-related quality of life. All outcomes will be measured at baseline, at 2, 4 weeks of treatment, and at the 2 month follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013101214980N1**

Registration date: **2013-11-23, 1392/09/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-23, 1392/09/02

Registrant information

Name

Mohammad Mazaheri

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2712

Email address

mohammad.mazaheri@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-03-11, 1392/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparable efficacy anise and corn starch in controlling symptoms in patients with Postprandial Distress Syndrome

Public title

Effect of Pimpinella Anise product in Postprandial Distress Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients within 18-65 years old with Postprandial Distress Syndrome. Exclusion Criteria: Using of chemical and herbal drugs; History of abdominal surgeries; History of bloody diarrhea; Pregnancy and lactation

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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**

Isfahan University of Medical Sciences

Street address

Hezargrib Ave.

City

Isfahan

Postal code**Approval date**

2013-08-23, 1392/06/01

Ethics committee reference number

292156

Health conditions studied**1****Description of health condition studied**

Dyspepsia

ICD-10 code

K30

ICD-10 code description

Indigestion

Primary outcomes**1****Description**

Severity Assessment of Dyspepsia

Timepoint

At baseline, at 2,4,12 weeks

Method of measurement

The Gastrointestinal Symptom Scale

2**Description**

Quality of life

Timepoint

At Baseline; at 12 Weeks

Method of measurement

SF-36 Questionnaire

Secondary outcomes**1****Description**

Side Effects

Timepoint

During the 12-week follow-up study

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intervention group: Pimpinella Anise 3g plus white sugar 1g ; For 4 weeks: Three times daily after meals

Category

Treatment - Drugs

2**Description**

placebo: Corn starch powder 3g plus white sugar 1g ; For 4 weeks, Three times a daily after meals

Category

Placebo

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

Digestive Health Center

Full name of responsible person

Mohammad Mazaheri

Street address

Shariati Ave.

City

Isfahan

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad bagher Minaee

Street addressTraditional Medicine Faculty: Behesht Ave: Vahdate
Islami Ave: Enghelab Square.**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

Mohammad Mazaheri

Position

Resident ph.D of Iranian Traditional Medicine

Other areas of specialty/work**Street address**Traditional Medicine Faculty: Behesht Ave: Vahdate
Islami Ave.**City**

Tehran

Postal code**Phone**

+98 31 1792 2712

Fax**Email**

mazaherimohammad@yahoo.com

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

Isfahan University of Medical Sciences

Full name of responsible person

Pyman Adibi

Position

Gastroenterologist

Other areas of specialty/work**Street address**Research Council of Isfahan University of Medical
Sciences**City**

Isfahan

Postal code**Phone**

+98 31 1792 3060

Fax**Email**

adibi@med.mui.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

Mohammad Mazaheri

Position

Resident ph.D of Iranian Traditional Medicine

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

Hezargrib Ave.

City

Isfahan

Postal code**Phone**

+98 31 1792 3060

Fax**Email**

mazaherimohammad@yahoo.com

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*