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)

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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
Isfehan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad bagher Minaee
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Traditional 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
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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