Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of compared of Apium Graveolence and Trachyspermum Copticum traditional product effect with placebo and omeprazol on clinical symptoms of 18 to 60 years old patients with Functional Dyspepsia

Protocol summary

Summary

This study is designed with the main aim to investigate the effect of Apium Graveolence and Trachyspermum Copticum traditional product on clinical symptoms of patients with Functional Dyspepsia, and will be performed as a randomized (Blocked randomization), double blind, placebo-control trial at one medical center in Iran; the studied groups include a group taking the Apium Graveolence and Trachyspermum Copticum traditional product, a group taking Omeprazole capsules, and a placebo group, each of which consisting of 50 FD patients, based on the ROME3 criteria. The main inclusion criteria is an age of 18 to 60 years old, whereas the main exclusion criteria is use of chemical and herbal drugs of functional dyspepsia; four weeks of administration of the drug or placebo will be conducted and a subsequent two-month follow-up observation of the primary and the secondary outcomes will be performed based on ranking the severity and frequency of gastrointestinal symptoms as well as the quality of life. Primary outcome time point will be at the baseline, 2nd, 4th, and 8th week, while the quality of life will be measured at the baseline, 4th and 8th week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092724228N1**
Registration date: **2016-06-03, 1395/03/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-03, 1395/03/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research Of Kerman University Of Medical Science

Expected recruitment start date
2015-12-22, 1394/10/01
Expected recruitment end date
2016-12-21, 1395/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Clinical trial of compared of Apium Graveolence and Trachyspermum Copticum traditional product effect with placebo and omeprazol on clinical symptoms of 18 to 60 years old patients with Functional Dyspepsia

Public title

Effect of Apium Graveolence and Trachyspermum

Copticum traditional product on clinical symptoms of patients with Functional Dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are 18 to 60 year-old patients with Functional Dyspepsia, without organic disorders on physical examination and endoscopy Exclusion criteria are Pregnancy and Lactation; History of convulsion; Active UTI; Use of chemical and herbal drugs of functional dyspepsia; use of anticoagulant drug;serious diseases like diabetes and cardiovascular diseases, Esophagus and gastrointestinal surgery, severe mental retardation, drug abuse, patient’s unwillingness to continue the project, not filling out the consent form History of peptic ulcer or reflux disease; Alarm sign (Weight loss, Anemia, Bloody stool, Dysphagia,etc

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

Ethics Committe of Kerman University of Medical Sciences

Street address

Shafa Crossroad; Jomhuri Boulevard; Kerman

City

kerman

Postal code

Approval date

2015-08-25, 1394/06/03

Ethics committee reference number

IR.KMU.REC.1394.233

Health conditions studied

1

Description of health condition studied

Functional Dyspepsia

ICD-10 code

K30

ICD-10 code description

Indigestion

Primary outcomes

1

Description

Severity assessment of dyspepsia

Timepoint

During 8 weeks follow up study

Method of measurement

The gastrointestinal symptom scale

2

Description

Quality of life

Timepoint

At baseline, 2, 4, 8 weeks

Method of measurement

NDI10 quality of life scale

Secondary outcomes

1

Description

Side effects

Timepoint

During 12 weeks follow up study

Method of measurement

Questionnair

Intervention groups

1

Description

Apium Graveolense beans 250 mg plus Trachyspermum Copticum beans 250 mg, two times daily,after meal

Category

Treatment - Drugs

2

Description

Corn starch 500 mg, two times daily, after meal

Category

Placebo

3

Description

Omeprazol 20 mg, daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipur Hospital

Full name of responsible person

Dr. Zahedi Mohammad Javad

Street address

Emam khomeini High way; kerman

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kerman University of Medical Sciences

Full name of responsible person

Pardakhti Abbas

Street address

Shafa Crossroad; Jomhuri Boulevard; Kerman

City

Kerman

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 of Kerman 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

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Full name of responsible person

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Position

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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