

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the efficacy of "Pistacia atlantica" resin (Bane) on clinical symptoms of patients with Functional Dyspepsia

Protocol summary

Summary

This study is designed to evaluate the efficacy of Pistacia atlantica Resin 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 Functional dyspepsia. This randomized, double-blind, placebo-controlled trial will be performed at one University center and will include Pistacia atlantica Resin and placebo (suger) group. Each group will consist of 48 Functional dyspepsia patients. four weeks of administration of Pistacia atlantica Resin or placebo will be conducted. During the subsequent 1 months, follow-up observations of primary and secondary outcomes will be performed. The primary outcomes and the secondary outcomes are differences as measured on the Nepean Dyspepsia Index for dyspepsia and on the questionnaire for Functional Dyspepsia-related quality of life. All outcomes will be measured at baseline, at 2, 4 weeks of treatment, and at the 1 month follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031327033N1**

Registration date: **2016-06-11, 1395/03/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-11, 1395/03/22

Registrant information

Name

Mahdiyehsadat Eftekharafzali

Name of organization / entity

Kerman University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of "Pistacia atlantica" resin (Bane) on clinical symptoms of patients with Functional Dyspepsia

Public title

The efficacy of Bane on patients with Functional Dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients within 18-60 years old with Functional Dyspepsia! No history of peptic ulcer or Reflux !The absence of an underlying disease, including heart failure, renal failure, cirrhosis, diabetes, hypothyroidism;

No history of abdominal surgeries :Exclusion Criteria:
Using of chemical and herbal drugs: Pregnancy and lactation

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **94**

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

City

kerman

Postal code

۰۰۹۸

Approval date

2016-06-01, 1395/03/12

Ethics committee reference number

IR.KMU.AH.REC.1395.10

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

at baseline, 2, 4, 8 weeks

Method of measurement

the gastrointestinal symptom scale

Secondary outcomes

1

Description

quality of life

Timepoint

at baseline, 2, 4, 8 weeks

Method of measurement

NDI10 quality of life scale

Intervention groups

1

Description

pistachia atlantica capsules 500 mg orally , twice daily for a month

Category

Treatment - Drugs

2

Description

Placebo capsules 500 mg orally , twice daily for a month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipur hospital

Full name of responsible person

Dr. zahedi mohammad javad

Street address

Emam high way

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman Medical University of Sciences

Full name of responsible person

Kerman Medical University of Sciences

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Jomhuri boulevard

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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

Kerman Medical University of 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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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