

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jul 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 Eftekharaftali

##### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3211 0360

##### Email address

m.eftekharaftali@kmu.ac.ir

##### 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  
**Street address**  
 Jomhuri boulevard  
**City**  
 Kerman  
**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

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 Kerman Medical University of 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