

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Evaluating Efficacy of traditional preparation containing *Bunium persicum* and *Coriandrum sativum* on clinical symptoms of patients with functional dyspepsia

Protocol summary

Study aim

Evaluating efficacy of traditional preparation *Bunium Persicum* and *Coriandrum Sativum* on clinical symptoms of patients with functional dyspepsia.

Design

A randomized, double-blind, placebo-controlled clinical trial as a pilot study with a sample size of 30 in each group

Settings and conduct

Bunium Persicum and *Coriandrum* seeds are prepared from a local Atari and are approved by the pharmacognosy specialist after approval of the species. First, wash the seeds of *Bunium Persicum* and *Coriandrum*, after cleansing and washing, in twice the volume of grape vinegar from Barij Essence Company for 24 hours. Then dry the mixture in the oven at 37 ° C for 24 hours. We roast and powder the dried seeds and after being passed through the screening of the mesh 30, the patient is given 500 mg capsules containing 250 mg of each *Bunium Persicum* and *Coriandrum* powder twice daily. Control capsules contain corn starch. The medicines are prepared and uniformly packaged and coded in the Faculty of Pharmacy of Kerman University of Medical Sciences. The person doing the coding has no role in the study until the end of the intervention. Patients by someone who is unaware of how the drugs are coded.

Participants/Inclusion and exclusion criteria

Patients 18-60 years old with functional dyspepsia based
Exclusion criteria: Pregnant patients Breastfeeding
People with allergies to ginger and similar herbs
Hemorrhagic diseases History of gastrointestinal ulcer or reflux disease IBS A history of surgery in the esophagus, stomach and intestines

Intervention groups

Intervention group : 250 mg of cumin powder, 250 mg of coriander powder, twice daily for 4 weeks Control

group: Capsule containing 500 mg of starch powder, twice daily for 4 weeks

Main outcome variables

quality of life

General information

Reason for update

Minor changes in methods

Acronym

IRCT registration information

IRCT registration number: **IRCT20190304042911N1**

Registration date: **2019-11-03, 1398/08/12**

Registration timing: **retrospective**

Last update: **2022-04-29, 1401/02/09**

Update count: **1**

Registration date

2019-11-03, 1398/08/12

Registrant information

Name

ali saeidpour parizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4230 6385

Email address

ali45asp@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-06, 1398/01/17

Expected recruitment end date

2019-10-09, 1398/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating Efficacy of traditional preparation containing Bunium persicum and Coriandrum sativum on clinical symptoms of patients with functional dyspepsia

Public title

Evaluating Efficacy of traditional preparation containing Bunium persicum and Coriandrum sativum on clinical symptoms of patients with functional dyspepsia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages 18-60 years Functional dyspepsia based on Rome 4 criteria and with a diagnosis of gastrointestinal specialty No exclusion criteria

Exclusion criteria:

Pregnant patients Lactation People with allergies to ginger, fennel, dill and other herbs similar Hemorrhagic diseases (due to the effect of cumin on slowing clot formation) History of gastrointestinal ulcer or reflux disease Irritable Bowel Syndrome History of surgery in the esophagus, stomach and intestines Any type of drug use, severe mental retardation Warning Signs (Weight Loss, Anemia, Stool Blood)

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were selected based on entry and exit criteria and after two weeks of non-use of the drug with blocked randomization method and entered into one of the two groups studied. Each patient takes a capsule twice a day, for one month, after breakfast and dinner, and then followed for one month.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the study, both the participants and the researchers are completely unaware of the way in which the drug and placebo are packaged, and pharmaceutical

packages are randomly distributed to patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Committee on Ethics in the Research Center of Afzali Pour-Kerman University of Medical Sciences.

Street address

Kerman, Imam Khomeini Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2019-02-28, 1397/12/09

Ethics committee reference number

IR.KMU.AH.REC.1397.157

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

Functional dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

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

Quality of life

Timepoint

Baseline, after 4, and 8 weeks

Method of measurement

Nepean dyspepsia quality of life questionnaire

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

Dyspepsia severity

Timepoint

Baseline, after 4, and 8 weeks

Method of measurement

Dyspepsia severity scale

2

Description

Dyspepsia frequency

Timepoint

Baseline, after 4, and 8 weeks

Method of measurement

Rome IV questionnaire

Intervention groups

1

Description

Intervention group: 250 mg cumin powder and 250 mg coriander seed, twice daily after meal, for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: Capsule containing 500 mg of starch powder, twice daily after meal, for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bessat Clinic One

Full name of responsible person

Ali Saeedpour Parizi

Street address

Tahmasb Abad intersection, Jihad Street, Bessat Clinic One

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3231 8000

Email

m.esfandiarpoor.87@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Kerman, Shafa intersection, Jomhoori Square

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3231 5041

Email

Abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mahboobeh Esfandiarpoor

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Alley 10, Shams Tabrizi Street, Khaju Town

City

Kerman

Province

Kerman

Postal code

7816854634

Phone

+98 34 4230 6385

Email

m.esfandiarpoor.87@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Ali Saeedpoor parizi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

South Millennium Street, Alley 2, Niloufar Complex,
Unit 2

City

Kerman

Province

Kerman

Postal code

7618617479

Phone

+98 34 3231 8000

Email

Ali45asp@yahoo.com

Province

Kerman

Postal code

7618617479

Phone

+98 34 3231 8000

Email

Ali45asp@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data contains the main consequence can be shared

When the data will become available and for how long

The access time will start 6 months after the results are published

To whom data/document is available

University and industry researchers

Under which criteria data/document could be used

If researchers want to do the same process

From where data/document is obtainable

Ali Saeedpoor provides the data. Ali45asp@yahoo.com

What processes are involved for a request to access data/document

The data will be sent as soon as possible after receiving a request from the researcher

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Ali Saeedpoor parizi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

South One Thousand and One Night Street, Alley 2,
Niloufar 2 Complex, Unit 2

City

Kerman