

# 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 Saeedpour 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