

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluating the efficacy of Persian medicine processed *Bunium persicum* on functional dyspepsia.

Protocol summary

Study aim

Evaluating the efficacy of Persian medicine processed *Bunium persicum* on functional dyspepsia.

Design

Randomized, superiority, controlled group trial with blinded outcome assessment with a parallel group design of 45 patients, Randomization by using the random block method, with a ratio of 1:1 and as one of the four blocks.

Settings and conduct

Kermani cumin seeds are prepared from a local herbal products shop and after confirming the quality and species of the sample by a pharmacognosy specialist, they are used in the preparation of the product. First, after cleaning and washing, we soak the seeds in twice the volume of Barij essence grape vinegar for 24 hours. Then dry the grain mixture in Aven at 37° C for 24 hours. Roast and powder the dried seeds and after passing through a 30 mesh sieve, it is supplied to the patient in the form of 500 mg capsules twice a day. Control group capsules contain corn starch. Drugs are prepared in the Faculty of Pharmacy of Kerman University of Medical Sciences and are packaged and coded in the same way. The person in charge of the coding has no role in the study until the end of the intervention. Patients will be selected by someone not knowing the coding method. This clinical trial is performed in Kerman Afzalipour hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients between 18 and 60 years old who are suffering from functional indigestion and do not have the exclusion criteria, who have consciously signed the consent form. Exclusion criteria: organic gastrointestinal disorders, use of anticoagulant, serious organic, or mental disorders.

Intervention groups

Intervention group: 500 mg cumin powder, twice a day for 4 weeks Control group: Capsules containing 500 mg of starch powder, twice a day for 4 weeks

Main outcome variables

Severity and frequency of dyspepsia, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210602051471N1**

Registration date: **2022-01-09, 1400/10/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**

Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Saeed Moghtaderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3251 0958

Email address

s.moghtaderi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-04, 1400/10/14

Expected recruitment end date

2022-07-05, 1401/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating the efficacy of Persian medicine processed Bunium persicum on functional dyspepsia.

Public title
Evaluating the efficacy of Bunium persicum on functional dyspepsia.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients between 18 and 60 years old who are suffering from functional indigestion and do not have the exclusion criteria. Who have consciously signed the consent form.
Exclusion criteria:
Organic gastrointestinal disorders use of anticoagulant drugs Serious organic, or mental disorders

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

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
The patients will enter the study using the random block method, with a ratio of 1:1 and as one of the four blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
The whole process of pharmacology will be done by a third person who does not have any role in finding patients and data analysis. The medicine and the placebo are packed similarly and after being given a code (as four blocks) will be available for the researcher. The data analysis will be conducted by a person who is not concerned about the groups under intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Afzalipour Hospital- Kerman University of Medical Sciences
Street address
Afzalipour Hospital, Emam khomeini Highway
City
Kerman
Province
Kerman
Postal code
7616913911
Approval date
2021-08-30, 1400/06/08
Ethics committee reference number
IR.KMU.REC.1400.300

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
Dyspepsia symptoms severity score
Timepoint
4 times: With arrival, after 2 , 4 and 8 weeks
Method of measurement
Dyspepsia symptoms severity questionnaire

2

Description
Dyspepsia symptoms frequency
Timepoint
4 times: With arrival, after 2 , 4 and 8 weeks
Method of measurement
Dyspepsia symptoms frequency questionnaire

3

Description
Quality of life
Timepoint
3 times: With arrival, after 4 and 8 weeks
Method of measurement
Dyspepsia quality of life questionnaire

Secondary outcomes

1

Description

Drug side effects

Timepoint

With arrival until the end of follow-up period

Method of measurement

Drug side effects questionnaire

Intervention groups

1

Description

Intervention group: Bunium persicum powder capsules, 500 mg, twice a day, for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: Corn starch capsules, 500 mg, twice a day, for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

مریم عطیمی

Street address

Emam Khomeini Highway, Afzalipour Hospital

City

Kerman

Province

Kerman

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7616913911

Phone

+98 34 3325 7651

Email

dr.azimm@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abas Pardakhti

Street address

Vice Chancellor for Research, Kerman University of Medical Sciences, Jahad St., Somayeh 4-way

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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

Saeed Moghtaderi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No. 7, 12th Alley, Abouzar St.

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7617875396

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Maryam Azimi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

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

Kerman University of Medical Sciences

Full name of responsible person

Saeed Moghtaderi

Position

Resident

Latest degree

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available