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: Capsule containing 500 mg of starch powder, twice daily for 4 weeks
Main outcome variables
Indigestion severity/ quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT20190304042911N1
Registration date: 2019-11-03, 1398/08/12
Registration timing: retrospective

Last update: 2019-11-03, 1398/08/12
Update count: 0

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
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

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: 50

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 minimization 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

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
Indigestion severity score

Timepoint
4 times: On arrival, 2, 4 and 8 weeks

Method of measurement
Gastrointestinal Symptom Rating Scale

Secondary outcomes
empty

Intervention groups

1

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

Category
Treatement - Drugs

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
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
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