Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Apium graveolense and Trachyspermum copticum versus Domperidone on clinical symptoms of patients with postprandial distress syndrome

Protocol summary

Study aim
Competition of efficacy of traditional remedy of Trachyspermum copticum and Apium graveolence with Domperidone tablet on clinical symptoms of patients with postprandial distress syndrome

Design
Clinical trial with community-based and control group, with parallel groups, double blind, randomized

Settings and conduct
Patients with Postprandial Distress Syndrome after referring to Afzalipour hospital, based on entry and non-entry criteria, randomly (block randomization) enter the study. Preparation, packaging and coding of drugs are done by the pharmacist, and patients and researcher are blind to the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - 18-60 years old patients - Patients with postprandial distress syndrome based on Rome IV criteria Non-entry criteria: - Pregnancy and lactation - History of gastrointestinal surgery - History of convulsion - Use of anti coagulant drugs - Use of other chemical or herbal medicine for dyspepsia.

Intervention groups
-Intervention group: traditional remedy of Trachyspermum copticum and Apium graveolence, 1 gr daily, for 4 weeks - Control group: Domperidone tablet 10 mg, 30 mg daily, for 4 weeks

Main outcome variables
Symptom severity and quality of life

General information

Reason for update
Change in the methods and start date

Acronym

IRCT registration information
IRCT registration number: **IRCT20150927024228N2**
Registration date: **2019-03-08, 1397/12/17**
Registration timing: **prospective**

Last update: **2023-01-29, 1401/11/09**
Update count: **3**

Registration date
2019-03-08, 1397/12/17

Registrant information

Name
Maryam Azimi

Name of organization / entity
Kerman University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
2020-02-01, 1398/11/12

Actual recruitment end date
2020-08-31, 1399/06/10

Trial completion date
2020-08-31, 1399/06/10

Scientific title
Efficacy of Apium graveolense and Trachyspermum copticum versus Domperidone on clinical symptoms of patients with postprandial distress syndrome

Public title
Efficacy of Apium graveolense and Trachyspermum copticum on postprandial syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18 to 60 year-old patients with functional dyspepsia Presence of symptoms of postprandial distress syndrome
Exclusion criteria:
Pregnancy and Lactation History of convulsion Use of chemical and herbal drugs of dyspepsia Serious diseases like diabetes and cardiovascular diseases History of gastrointestinal surgery Severe mental retardation Drug abuse Use of anticoagulant drug History of side effects related to use of herbal or chemical medicines History of peptic ulcer or gastrointestinal reflux disease Presence of any structural disorder in endoscopy during the last three months Presence of irritable bowel syndrome The patient's unwillingness to continue the study, or unwillingness to signing the concent form Presence of any alarming sign (severe weight loss, anemia, bloody stool, difficult swallowing
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Actual sample size reached: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are referred to a group of 6 blocks with 4 random sequences, respectively. Sequences are based on the repetition of each of the two groups A, and B 6 blocks are randomly placed on the list. The patient will be referred to the list, respectively. for example: AABB, ABAB,..
Blinding (investigator's opinion)
Double blinded
Blinding description
Medications are packaged and encoded by a third person who does not have a role until the end of the study and the researcher does not know about encoding. The general nature of the intervention groups is described to the patients before starting the study, But there is no information about the details of the group in which they are located.
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; Kerman
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2018-05-28, 1397/03/07
Ethics committee reference number
IR.KMU.REC.1397.069

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
Severity assessment of dyspepsia
Timepoint
4 times: baseline, 2,4 and 8 weeks
Method of measurement
The gastrointestinal severity symptom scale

2

Description
Quality of life
Timepoint
3 times: baseline, 4, 8 weeks
Method of measurement
NDI10 quality of life scale

3

Description
Frequency assessment of dyspepsia
Timepoint
4 times: baseline, 2,4 and 8 weeks

Method of measurement
Rome IV questionnaire

Secondary outcomes

1

Description
Side effects
Timepoint
During 8 weeks study
Method of measurement
Side effects questionnnaire

Intervention groups

1

Description
Intervention group: Apium Graveolense beans 110 mg plus Trachyspermum Copticum beans 110 mg, three times daily,after meal, for 4 weeks
Category
Treatment - Drugs

2

Description
Control group: Domperidone tablet 10 mg, three times daily, after meal, for 4 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipur Hospital
Full name of responsible person
Maryam Azimi
Street address
Emam khomeini High way; kerman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Pardakhti Abbas
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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
Maryam Azimi
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Articles

When the data will become available and for how long
6 months after printing of Articles

To whom data/document is available
Academic and Industrial Researchers

Under which criteria data/document could be used
Demographic and symptom severity and quality of life information

From where data/document is obtainable
E-mail

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

Comments