Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study the efficacy of an iranian traditional herbal compound in treatment of functional dyspepsia, add-on double blind randomized controlled trial

Protocol summary

Study aim

Determining the effect of a traditional Iranian herbal compound in treatment of functional dyspepsia.

Design

A double-blind clinical trial with parallel groups is performed on 150 patients (105 in the drug group and 45 in the placebo group); Randomization is done by block randomization. Random Sequence generation will also be done using Randomizer software.

Settings and conduct

Patients of dyspepsia who have not responded to common treatments of internist or gastroenterologist in Imam Reza specialized clinic in Shiraz will be referred to enter the plan. After the patient enters, the block related to him is determined by the questioner and from that block he gives a code to the patient and delivers 28 sachets with that code to the patient.The place of questioning and providing medicine is Imam Reza specialized clinic in Shiraz. Participants & service providers are blinded to the intervention. The pharmacologist and statistician are aware of the contents of the sachets (drug or placebo).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women with one of the symptoms of ROME4 criteria for dyspepsia those are between 18-65 years old. Exclusion criteria: dyspepsia with organic causes, pregnant women, having plan to conceive through the study duration, lactating women, positive history of chronic liver diseases, renal diseases, malignancies and diabetes, taking anticoagulants including warfarin, Plavix, aspirin and other chemical agents, and herbal remedies that may be considered as confounding factors for this study: History of allergic reaction to components of drug and placebo.

Intervention groups

Drug group that receive sachets containing the drug composition. Placebo group that receive the sachet containing the placebo.

Main outcome variables

Reduction of "postprandial fullness", "postprandial satiety", "epigastric pain" and "epigastric burning"

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220304054179N1**
Registration date: **2022-04-13, 1401/01/24**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-13, 1401/01/24**
Update count: **0**

Registration date

2022-04-13, 1401/01/24

Registrant information

Name

soodabeh samimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3624 8075

Email address

samimisoodabeh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-12, 1400/12/21

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study the efficacy of an iranian traditional herbal compound in treatment of functional dyspepsia, add-on double blind randomized controlled trial

Public title
The efficacy of an iranian traditional herbal compound in treatment of dyspepsia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-65 years old Men and women Patients with one of the symptoms of ROME4 dyspepsia.
Exclusion criteria:
Dyspepsia with organic causes Pregnant women, having plan to conceive through the study duration Lactating women Positive history of chronic liver diseases, renal diseases, diabetes and malignancies Taking anticoagulants including warfarin, Plavix, aspirin and other chemical agents, and herbal remedies that may be considered as confounding factors for this study. Positive history of allergic reaction to "Anise", "Fennel", "Trachyspermum", "Caraway" and "Placebo composition"(Corn and wheat and barley).

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
This study is an add-on double blind randomized controlled trial study, and only statisticians know which code is drug or placebo and the questioner and patient are blinded. randomized allocation is done using block randomization; In blocking, variables such as age and sex and routine drug use and severity of symptoms will be considered. Random Sequence generation will also be done using Randomizer software. After the patient enters, the necessary explanations about the plan are provided to him and then his consent is received in the form of consent and his registration is done, based on the variables related to blocking (such as age, sex and routine medication) He is assigned, and from the codes in that block, a code is randomly assigned to the patient and the sachet with that code is delivered to the patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants & Questioner are blinded by the end of the project. The pharmacologist is aware of the contents of the sachets (drug or placebo). The statistician who prepares the blocks and tables of random numbers is aware of the content of the codes (drug or placebo).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Shiraz University of Medical Sciences

Street address
Zand Ave.

City
Shiraz

Province
Fars

Postal code
۱۴۳۳۶ - ۷۱۳۴۸

Approval date
2022-01-17, 1400/10/27

Ethics committee reference number
IR.SUMS.MED.REC.1400.570

Health conditions studied

1

Description of health condition studied
Dyspepsia

ICD-10 code
K30

ICD-10 code description
Functional dyspepsia

Primary outcomes

1

Description
Postprandial fullness

Timepoint
2 weeks

Method of measurement
Gastrointestinal Symptoms Severity Questionnaire

Secondary outcomes

1

Description
Epigastric pain&burning sensation
Timepoint
2 weeks
Method of measurement
Gastrointestinal Symptoms Severity Questionnaire

Intervention groups

1

Description
Intervention group: This group receives the drug, which contains a traditional herbal composition. the components of the product include the seeds of the anise plant and the seeds of the fennel plant and the seeds of the Trachyspermum plant and the seeds of the caraway plant, which are grinded and placed in 8-gram sachets by traditional medicine pharmacist in the drug manufacturing center located in Emam Reza Clinic. Each patient is given 28 sachets. The method of taking the medicine is one sachet in the morning before breakfast and one sachet at night at bedtime, which is consumed with half a glass of water, and the treatment period is two weeks.
Category
Treatment - Drugs

2

Description
Control group: The group that receives placebo. The placebo includes corn starch, wheat bran and barley flakes and 10% of the herbal composition of the drug (to simulate the appearance of the drug), which is prepared by a traditional medicine pharmacist in the drug manufacturing center located in Emam Reza Clinic in Shiraz and placed in 8 gram sachets.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam-reza clinic
Full name of responsible person
Soodabeh samimi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Soodabeh Samimi
Position
Student
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
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
Yes - There is 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 is potentially shareable after unidentifiable individuals.
When the data will become available and for how long
Access period starts 6 months after the results are published.
To whom data/document is available
All researchers can apply for data or other study documentation.
Under which criteria data/document could be used
Any use of the data, analysis or copying must be done with the permission of the researcher and with respect to his intellectual rights.
From where data/document is obtainable
Soodabeh Samimi, 09177921159, samimisoodabeh@sums.ac.ir
What processes are involved for a request to access data/document
The review and response to the applicant will take a maximum of one month.
Comments