Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of traditional Persian remedy of Melissa officinalis, Rosa damascena and Pimpinella anisum on clinical symptoms of patients with irritable bowel syndrome constipation-predominant (IBS-C).

Protocol summary

Study aim
Determining the efficacy of Persian medicine remedy of Melissa officinalis, Rosa damascene, and Pimpinella anisum in patients with constipation-predominant Irritable Bowel Syndrome compared with placebo.

Design
Phase 3 controlled clinical trial with a parallel design, double-blind, blocked randomization, with a sample size of 96 was designed.

Settings and conduct
This study would be performed at the Kerman clinic of gastrointestinal diseases in Afzalipour hospital. After visiting by a gastroenterologist, patients with IBS symptoms that has inclusion criteria and has fulfilled consent form would be randomly divided into two groups. Patients and researchers would be blind up to the end of the analysis

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18-60 years constipation-predominant irritable bowel syndrome according to Rome IV criteria syndrome; Exclusion criteria: pregnancy, and breastfeeding, hypothyroidism, severe complications related to this study, use of other effective drugs on irritable bowel syndrome (symptoms, quality of life, anxiety, and depression)

Intervention groups
Patients are divided into two groups: Persian medicine remedy of Melissa officinalis, Rosa damascene, and Pimpinella anisum; placebo

Main outcome variables
IBS - Severity symptoms; quality of life of patients with IBS

General information

Reason for update
Update information (final sample size, outcomes, intervention details,...)

Acronym

IRCT registration information
IRCT registration number: **IRCT20150927024228N4**
Registration date: **2021-06-14, 1400/03/24**
Registration timing: **prospective**

Last update: **2024-02-03, 1402/11/14**
Update count: **1**

Registration date
2021-06-14, 1400/03/24

Registrant information

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Name of organization / entity
Kerman University Of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-07, 1400/07/15

Expected recruitment end date
2022-05-09, 1401/02/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of traditional Persian remedy of Melissa officinalis, Rosa damascena and Pimpinella anisum on clinical symptoms of patients with irritable bowel syndrome constipation-predominant (IBS-C).

Public title
Efficacy of traditional Persian remedy of Melissa officinalis, Rosa damascena and Pimpinella anisum in patients with irritable bowel syndrome constipation-predominant (IBS-C).

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18-60 years old patients with constipation-predominant irritable bowel syndrome according to Rome IV criteria.

Exclusion criteria:
Pregnancy, and breastfeeding Hypothyroidism Severe complications related to this study use of other effective drugs on irritable bowel syndrome (symptoms, quality of life, anxiety, and depression)

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: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
According to block randomization, patients will be randomly entered into the study via blocks with size of 4 and 6, generated with Microsoft Excel® software. a trained secretory, who is blinded in details of the study, places patients in two groups based on these blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs are packaged into two groups (A and B) by a person that won't participate in the study. Patients, researchers, physicians, and all persons that participate in collecting, and analyzing data would be blinded. After analysis, the package contents will be announced. the herbal drug and placebo are prepared in the same package in terms of color, shape, and smell in the form of 500 mg capsules.

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
Afzalipour hospital, Emam Khomeini highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
۷۶۱۶۹۱۳۹۱۱

Approval date
2019-05-06, 1398/02/16

Ethics committee reference number
IR.KMU.AH.REC.1398.214

Health conditions studied

1

Description of health condition studied
Irritable Bowel Syndrome

ICD-10 code
K58.9

ICD-10 code description
Irritable bowel syndrome without diarrhea

Primary outcomes

1

Description
IBS symptom severity score

Timepoint
At the beginning of the intervention, after 4 weeks

Method of measurement
IBS symptom severity score questionnaire

2

Description
Quality of life of IBS patients

Timepoint
At the beginning of the intervention, after 4 weeks

Method of measurement
Quality of life questionnaire of IBS patients

3

Description
Anxiety and depression

Timepoint

At the beginning of the intervention, after 4 weeks

Method of measurement

Anxiety and depression questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Aqueous extract of capsules of Melissa officinalis, and Pimpinella anisum; and Rosa damascene powder manufactured in the School of Pharmacy of Kerman University of Medical Sciences, two times a day, each time one 500 mg capsule, half an hour before each meal, with one glass of water, for one month

Category

Treatment - Other

2

Description

Corn Starch-containing capsules, manufactured in the School of Pharmacy of Kerman University of Medical Sciences, two times a day, each time one 500 mg capsule, half an hour before each meal with one glass of water, for one month

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Afzalipour hospital

Full name of responsible person

Omid Eslami

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Afzalipour hospital, Emam Khomeinin highwey, Kerman, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

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Vice chancellor for research, Kerman University of Medical Sciences, Ibn Sina street, Jahad boulevard, Kerman, Iran

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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

Azimi Maryam

Position

Assistant professor of Kerman University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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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