

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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 damascena*, 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 damascena*, 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

Name

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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 secretary, 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 Committee 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

Street address

Afzalipour hospital, Emam Khomeinin highway,
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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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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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Person responsible for updating data

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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