

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of efficacy of two traditional medicine, Zataria multiflora Boiss and trachyspermum Copticum (L.) Link, on Clinical symptom in patient with Irritable bowel syndrome (IBS)

Protocol summary

Study aim

The aim of the study was to evaluate the efficacy of the Zataria Multiflora and Trachyspermum Copticum capsule on clinical signs of patients with IBS compared with Mebeverine and placebo

Design

The study is a randomized double-blind placebo controlled clinical trial

Settings and conduct

The patients referring to Kerman Besat Clinic are observed by the specialist. Patients who pass inclusion criteria complete the Consent form and enter the study. Drugs are packaged and they are named A, B and C by the person who is not involved in the study. Investigator and patients will be kept unaware to the treatment each patient will receive.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 60 years; Patients with IBS according to Rome III criteria for IBS; Completion of the consent form. Exclusion criteria: any chronic diseases, systemic warning signs, specific psychological and psychiatric diseases, history of abdominal surgery, familial history of gastrointestinal cancers or inflammatory bowel disease, pregnancy and breastfeeding (for women), weight loss more than 5-6% in the past month and abnormal laboratory tests

Intervention groups

Intervention group 1: receiving 750 mg of Zataria multiflora Boiss and Trachyspermum copticum , Intervention group 2: receiving 133 milligrams of Mebeverine. Control group: receiving placebo

Main outcome variables

Severe abdominal pain; Abdominal pain; Bloating rate; Satisfaction with bowel habits; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039707N1**

Registration date: **2018-12-01, 1397/09/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-01, 1397/09/10**

Update count: **0**

Registration date

2018-12-01, 1397/09/10

Registrant information

Name

Hossein Jamalizadeh tajabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3212 2239

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of two traditional medicine, Zataria multiflora Boiss and trachyspermum Copticum (L.) Link, on Clinical symptom in patient with Irritable bowel syndrome (IBS)

Public title

Comparison of efficacy of Traditional Medicine (Zataria multiflora Boiss. and Trachyspermum Copticum (L.) Link) on Clinical symptom in patient with Irritable bowel syndrome (IBS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

fulfilling Rome III criteria for IBS Completion of the consent form Being at the age of 18 to 60 years old

Exclusion criteria:

Pregnancy Breast feeding History of gastrointestinal surgery Any serious drug-related inverse effect Inevitable weight loss History of any diseases like Crohn's disease and ulcerative colitis Dyspepsia Severe mental retardation Any kind of substance abuse or alcohol consumption Not completing the consent form The occurrence of warning signs (weight loss, anemia, Hematochezia or melena, dysphagia)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple Randomization is done. The first patient receives drug A; The second patient receives drug B and the third patient receives drug C. This cycle is repeated.

Blinding (investigator's opinion)

Double blinded

Blinding description

The medicine is prepared and coded by a third person at the Faculty of Pharmacy in Kerman University of Medical Sciences. Then it is presented to the researcher and the researcher gives it to the patient. The patient and the researcher are not informed (blind) about the drug. The drug results will be decoded after extracting of the results.

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

Besat Clinic, Jahad Street

City

Kerman

Province

Kerman

Postal code

7619837773

Approval date

2018-09-14, 1397/06/23

Ethics committee reference number

IR.KMU.AH.REC.1397.082

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Quality of Life (QOL)

Timepoint

before the intervention, after 4 weeks, after 6 weeks (2 weeks after the interrupting the intervention)

Method of measurement

The quality of life questionnaire (IBS-QOL-34)

2

Description

pain

Timepoint

before the intervention, after 4 weeks, after 6 weeks (2 weeks after the interrupting the intervention)

Method of measurement

Visual Analogue Scale

3

Description

flatulence

Timepoint

before the intervention, after 4 weeks, after 6 weeks (2 weeks after the interrupting the intervention)

Method of measurement

Visual Analogue Scale

4**Description**

constipation

Timepoint

before the intervention, after 4 weeks, after 6 weeks (2 weeks after the interrupting the intervention)

Method of measurement

Visual Analogue Scale

5**Description**

diarrhea

Timepoint

before the intervention, after 4 weeks, after 6 weeks (2 weeks after the interrupting the intervention)

Method of measurement

Visual Analogue Scale

6**Description**

difficulty in bowel movements

Timepoint

before the intervention, after 4 weeks, after 6 weeks (2 weeks after the interrupting the intervention)

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: consuming 750 mg capsule (Zataria multiflora Boiss and Trachyspermum Copticum (L.) Link), BID(in the morning and in the evening before meals) for 4 weeks. The response to the treatment, quality of life and the severity of symptoms are checked in each patient. This response is investigated using questionnaire before and 4 and 6 weeks after intervention.

Category

Treatment - Drugs

2**Description**

Placebo group: consuming 750 mg capsule (Corn starch), BID (in the morning and in the evening before meals) for 4 weeks. The response to the treatment, quality of life and the severity of symptoms are checked in each

patient. This response is investigated using questionnaire before and 4 and 6 weeks after intervention.

Category

Placebo

3**Description**

Intervention group 2: 133 mg capsule(Mebeverine), BID(in the morning and in the evening before meals) for 4 weeks. The response to the treatment, quality of life and the severity of symptoms are checked in each patient. This response is investigated using questionnaire before and 4 and 6 weeks after intervention.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Specialized Clinic

Full name of responsible person

Hossein Jamalizade

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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
Hossein Jamalizadeh Tajabadi
Position
Ph.D Student of Persian Medicine
Latest degree
Medical doctor
Other areas of specialty/work
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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

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

After the study, information on the main outcome will be shared

When the data will become available and for how long

starting 9 months after publication

To whom data/document is available

All researchers can apply to receive it.

Under which criteria data/document could be used

Data and results will be available to all researchers in

order to continue the research and implementation of the irritable bowel after the publishing of results.

From where data/document is obtainable

email addresses: hjamalizadeh_14@yahoo.com

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

after checking Confirmation of demand, file(s) will be offered during 1 weak

Comments