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 Tracheyspermum 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)

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+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 Siences

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
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
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
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
Traditional Medicine
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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