# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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)
**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 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
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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 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**
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**