Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effect of Valerian (Valeriana officinalis) supplementation on the symptoms severity and quality of life in patients with irritable bowel syndrome: A randomized and double-blind clinical trial

Protocol summary

Study aim

Investigating the effect of valerian supplement (Valeriana officinalis) on the symptoms severity and quality of life in patients with irritable bowel syndrome (IBS)

Design

parallel-group, double-blind, randomized clinical controlled trial

Settings and conduct

After signing the consent form, 50 patients diagnosed with IBS will be randomly allocated into two groups to receive dried Valerian capsules (500 mg) or a placebo twice daily for eight weeks. Participants and researchers will be blinded with packages of Valerian or placebo coding with A or B with the same appearance. Outcomes will be assessed, through standard and valid questionnaires, at the beginning and the end of the study. All participants will be advised to follow a diet with low FODMAPs. Also, to control participants in terms of taking supplements and placebo and prevent the samples from falling, the follow-up of patients would occur every two weeks by phone.

Participants/Inclusion and exclusion criteria

1- Age 25 to 60 years2- Patients with irritable bowel syndrome according to the diagnosis of a gastroenterologist according to ROME-IV criteria (presence of heartache at least one day a week during the last 3 months in connection with at least two of the following cases: 1- problems with excretion 2- change in the frequency of defecation, 3- change in the shape and consistency of stool, and the absence of pathological findings in digestive examinations) 3- Suffering from certain diseases such as any active stomach-enteric disease or taking certain medicines 4- having an allergy to herbal products

Intervention groups

participants in the intervention group will receive dried valerian capsules (500 mg) twice daily for eight weeks. They receive advice and diet based on consuming foods containing low FODMAP.

Main outcome variables

IBS symptoms severity score and quality of life

General information

Reason for update

We changed the minimum age of patients to be included in the study (inclusion criteria) from 25 to 18 years. We increased the age range due to better access to patients. Also, the minimum age of 18 years is considered in several studies.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210427051098N3**
Registration date: **2023-11-18, 1402/08/27**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-23, 1404/12/04**
Update count: **1**

Registration date

2023-11-18, 1402/08/27

Registrant information

Name
Sayyed Saeid Khayyatzadeh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01
Expected recruitment end date
2024-03-10, 1402/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of Valerian (Valeriana officinalis) supplementation on the symptoms severity and quality of life in patients with irritable bowel syndrome: A randomized and double-blind clinical trial

Public title
Evaluating the effect of Valerian on irritable bowel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1- Age 18 to 65 years 2- Patients with irritable bowel syndrome according to the diagnosis of a gastroenterologist according to ROME-IV criteria
Exclusion criteria:
Dietary changes during the study Unwillingness to continue attending the study Pregnancy or breastfeeding during the study Hospitalization Suffering from certain diseases such as any active stomach-enteric disease or taking certain medicines Having an allergy to herbal products
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
After determining the eligible people and obtaining their consent, the participants will be divided into two groups [intervention (valerian) or control (starch)] by random allocation method. Firstly, each individual will receive a specific code number. Then all code numbers will be entered into random allocation software. Software inputs will include the total number of samples and the number of treatment groups (intervention and control). The software output will include random numbers assigned to two groups. The allocation ratio will be 1:1. Each participant will have an equal chance of being in each group, and participants in the study will not be able to predict the type of intervention they receive.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, researchers and patients will be blinded using supplements or placebos that have the same appearance and the same packaging. Coding is done by someone outside the study. The given codes will be provided to the researchers after the statistical analysis of the data and for writing the article. The codes will be defined as A and B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences
Street address
Ethics Committee of Shahid Sadoughi University of Medical Sciences, Shahid Sadoughi University of Medical Sciences and Health Services Campus- Shohadaye Gomnam Blvd- Alem Square- Yazd
City
Yazd
Province
Yazd
Postal code
8915173160
Approval date
2023-09-11, 1402/06/20
Ethics committee reference number
IR.SSU.SPH.REC.1402.066

Health conditions studied

1

Description of health condition studied
Symptoms Severity and quality of life in patients with irritable bowel syndrome
ICD-10 code
k58.8
ICD-10 code description
Other and unspecified irritable bowel syndrome

Primary outcomes

1

Description
Symptoms severity of irritable bowel syndrome
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
IBS-Severity Scoring System (IBS-SSS) questionnaire.

2

Description
The quality of life in patients with irritable bowel syndrome
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Irritable Bowel Syndrome Quality of Life Questionnaire

Secondary outcomes

1

Description
Anxiety and depression
Timepoint
At the beginning of the study and after 8 weeks of the intervention
Method of measurement
Hospital Anxiety and Depression Scale questionnaire

2

Description
Visceral Sensitivity
Timepoint
At the beginning of the study and after 8 weeks of the intervention
Method of measurement
Visceral Sensitivity Index questionnaire

3

Description
Patient Health
Timepoint
At the beginning of the study and after 8 weeks of the intervention
Method of measurement
Patient Health Questionnaire (PHQ)-12

4

Description
Sleep quality
Timepoint
At the beginning of the study and after 8 weeks of the intervention
Method of measurement
Pittsburgh Sleep Quality Index questionnaire (PSQI)

Intervention groups

1

Description
Intervention group: 500 mg capsule of dried Valerian (Valeriana officinalis) powder twice daily (1000 mg overall)
Category
Treatment - Other

2

Description
Control group: 500 mg capsule of starch powder twice daily (1000 mg overall)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Research Institute for gastroenterology and liver diseases of shahid beheshti university of medical
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Zohreh Khosravani Shooli
Position
MSc student in Nutrition
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document

The non-identifiable statistical data of the participants will be shared collaboratively.

When the data will become available and for how long

Access will be provided upon publication of the relevant study article.

To whom data/document is available

Researchers at scientific institutions.

Under which criteria data/document could be used

Studies in the field of irritable bowel syndrome.

From where data/document is obtainable

To receive the documents through email, please send your request and the reason for it to person responsible for general inquiries of the study. After reviewing it in the shortest possible time, a response to your request will be sent. Email address: zoh.khosravani@gmail.com

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

Via email. zoh.khosravani@gmail.com

Comments