

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the efficacy of Valerian and placebo in patients with irritable bowel syndrome

#### Protocol summary

##### Study aim

Assessment of effect of valerian on irritable bowel syndrome (IBS)

##### Design

A phase 2 clinical trial on 40 patients, with a control group, parallel groups, double-blind, randomized design. For simple randomization random.org website was used.

##### Settings and conduct

In this study, patients suffering from IBS who are admitted to Boali hospital in Tehran and have the inclusion criteria, will enter to the study. Patients will be divided randomly in two groups. In the intervention group, Sedamin capsules daily and in control group one placebo capsule a day will be added to the main treatment regimen for 4 weeks. Abdominal pain (severity of pain and Duration of pain), Abdominal distension (bloating, swollen or tight tummy), Satisfaction with fecal excretion, Improving patients symptoms and Quality of life is assessed by the questionnaire before the intervention and one month after the intervention and will be completely reviewed at the end of the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with irritable bowel syndrome based on Rome IV criteria Age between 18-65 years old Informed consent. Exclusion criteria: Pregnant women, Lactating women, Having liver and kidney failure, Having an allergy or previous side effects to Valerian, Having diabetes, People receiving neuroleptics, People taking valerian other than our study program

##### Intervention groups

Intervention group: In this group, patients will receive Sedamin capsules (Contains 530 mg Valerian) produced by Goldaru Pharmaceutical Company (Tehran, Iran) once a day for 4 weeks in addition to their standard treatment.

##### Main outcome variables

Abdominal pain (severity of pain and duration of pain); Abdominal distension (bloating, swollen or tight tummy); Satisfaction with fecal excretion; The impact of the IBS on the Patient's Quality of Life; Irritable Bowel Syndrome

Severity Score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160813029327N21**

Registration date: **2023-05-09, 1402/02/19**

Registration timing: **prospective**

Last update: **2023-05-09, 1402/02/19**

Update count: **0**

##### Registration date

2023-05-09, 1402/02/19

##### Registrant information

##### Name

Ramin Abrishami

##### Name of organization / entity

Islamic Azad University, Pharmaceutical sciences branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2264 1889

##### Email address

r\_abrishami@iaups.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-22, 1402/03/01

##### Expected recruitment end date

2024-05-21, 1403/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the efficacy of Valerian and placebo in patients with irritable bowel syndrome

**Public title**  
Assessment of effect of valerian on Irritable Bowel Syndrome (IBS)

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with irritable bowel syndrome based on Rome IV criteria Age between 18-65 years old Informed consent  
**Exclusion criteria:**  
Pregnant women Lactating women Having liver and kidney failure Having an allergy or previous side effects to Valerian Having diabetes People receiving neuroleptics People taking valerian other than our study program

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Random number table: Two groups of 30 patients were made using simple randomization method, based on Random Sequence Generator via www.random.org website. For Random Allocation concealment, the method of opaque sealed envelopes with random sequence was used. Patients were allocated in one of two groups based on their entry sequence.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study both researcher and patients are not aware which medication the patient is using. Drugs will be dispensed by researcher in uniform packages with unique codes.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Islamic Azad University of Tehran  
Medical Science

##### Street address

No. 99, The First of Yakhchal Ave., Shariati St,  
Gholhak

##### City

Tehran

##### Province

Tehran

##### Postal code

1941933111

#### Approval date

2023-02-12, 1401/11/23

#### Ethics committee reference number

IR.IAU.PS.REC.1401.433

## 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

Abdominal Pain (Severity of pain and Duration of pain)

#### Timepoint

Before intervention and 4 weeks after intervention

#### Method of measurement

Irritable Bowel Severity Scale (IBSS)

### 2

#### Description

Abdominal distension (Bloating, Swollen or Tight tummy)

#### Timepoint

Before intervention and 4 weeks after intervention

#### Method of measurement

Irritable Bowel Severity Scale (IBSS)

### 3

#### Description

Satisfaction with fecal excretion

#### Timepoint

Before intervention and 4 weeks after intervention

#### Method of measurement

Irritable Bowel Severity Scale (IBSS)

#### 4

##### **Description**

The impact of the IBS on the Patient's Quality of Life

##### **Timepoint**

Before intervention and 4 weeks after intervention

##### **Method of measurement**

Irritable Bowel Severity Scale (IBSS)

#### 5

##### **Description**

Irritable Bowel Syndrome Severity Score

##### **Timepoint**

Before intervention and 4 weeks after intervention

##### **Method of measurement**

Irritable Bowel Severity Scale (IBSS)

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

##### **Description**

Intervention group: In this group, patients will receive Sedamin capsouls produced by Goldaroo Pharmaceutical Company once a day for 4 weeks plus their standard treatment.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Control group: In this group, patients will receive Placebo capsouls once a day for 4 weeks plus their standard treatment.

##### **Category**

Placebo

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Booali hospital

###### **Full name of responsible person**

Sheyda Aghajani

###### **Street address**

the beginning of Damavand street, Imam Hossein square.

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1711734365

###### **Phone**

+98 21 3334 8036

##### **Fax**

+98 21 3378 6182

##### **Email**

booali.hospital96@gmail.com

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Islamic Azad University

###### **Full name of responsible person**

Farshad Hashemian

###### **Street address**

No. 99, Yakhchal Ave, Shariati St.

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1941933111

###### **Phone**

+98 21 2264 0051

###### **Email**

fhashemian@yahoo.com

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Islamic Azad University

##### **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**

Islamic Azad University

###### **Full name of responsible person**

Ramin Abrishami

###### **Position**

Associate professor

###### **Latest degree**

Specialist

###### **Other areas of specialty/work**

Medical Pharmacy

###### **Street address**

No. 99, Yakhchal Ave, Shariati St.

###### **City**

Tehran

**Province**  
Tehran  
**Postal code**  
1941933111  
**Phone**  
+98 21 2264 1889  
**Fax**  
+98 21 2264 1889  
**Email**  
r\_abrishami@iaups.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Ramin Abrishami  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
No. 99, Yakhchal Ave, Shariati St.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1941933111  
**Phone**  
+98 21 2264 1889  
**Fax**  
+98 21 2264 1889  
**Email**  
r\_abrishami@iaups.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Sheyda Aghajani  
**Position**  
Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Medical Pharmacy

**Street address**  
No. 99, The First of Yakhchal Ave., Shariati St.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1941933111  
**Phone**  
+98 21 2264 0051  
**Email**  
Sheida.aghajani96@gmail.com

## 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

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

### Title and more details about the data/document

Information about the primary outcome will be shared after Deidentification of Individual Participant Data

### When the data will become available and for how long

after publication of paper, for two years

### To whom data/document is available

Academic persons

### Under which criteria data/document could be used

Academic or clinical use. users should cite the primary document

### From where data/document is obtainable

via email to corresponding author

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

Submission of valid and formal documentation of affiliation to the Academic Center, Explanation about how to use the information and the purpose of request

### Comments