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 wasused.

Settings and conduct
In this study, patients suffering from IBS who are admitted to Booali 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 capsouls daily and in control group one placebo capsoul 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 months after the intervention and will be completely reviewed at the end of the study.

Participants/Inclusion and exclusion criteria
Inclution criteria: Patients with irritable bowel syndrome based on Rome IV criteria Age between 18-65 years old Informed consent. Exclution 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, Pharamceutical 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 lrritable 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
Submition of valid and formal documentation of affiliation to the Academic Center, Explaination about how to use the information and the purpose of request
Comments