

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Evaluation of total black seed (*nigella sativa*) extract efficacy in patients with irritable bowel syndrome

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of total black seed extract in patients with irritable bowel syndrome

##### Design

Clinical trial with control group with parallel, double-blind, randomized, on 160 patients, which uses random blocks for randomization with the help of online software at [www.sealedenvelope.com](http://www.sealedenvelope.com)

##### Settings and conduct

The patients referred to the gastrointestinal clinic, Ahvaz, based on the IBS diagnostic criteria, were randomly divided into two groups of case and control and received routine treatments and capsules. The patients and physicians are not aware of the type of medications. Patients are thoroughly examined and questionnaires are filled out. During the three months of receiving the drug, patients are followed up every two weeks and symptoms are recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of irritable bowel syndrome based on Roma IV diagnosis criteria; People 18 to 50 years old and if they are over 50 years old, colonoscopy should be screened to make sure there are no other diseases and malignancies; No pregnancy; No malignancies (carcinoid and colorectal tumors), celiac disease, diverticulitis, gastrointestinal infections, hyper and hypothyroidism, lactose intolerance, IBD and ischemic colitis; No previous use of drugs, calcium channel blockers and antidepressants; No history of allergy to plant compounds of the black seed family. Exclusion criteria: Sensitivity to the drug used in this study; Dissatisfaction with participating in the study;

##### Intervention groups

Intervention group: Use of black seed extract as a capsule with irritable bowel syndrome. Control group: Use of placebo capsules with irritable bowel syndrome.

##### Main outcome variables

Abdominal pain severity; abdominal distension severity; satisfaction with defecation habit; quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160709028845N1**

Registration date: **2022-03-07, 1400/12/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-03-07, 1400/12/16**

Update count: **0**

##### Registration date

2022-03-07, 1400/12/16

##### Registrant information

##### Name

Nima Bakhtiarri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3392 9324

##### Email address

bakhtiarri.n@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-20, 1400/12/01

##### Expected recruitment end date

2022-05-22, 1401/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of total black seed (nigella sativa) extract efficacy in patients with irritable bowel syndrome

**Public title**

The effect of black seed on irritable bowel syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of Irritable Bowel Syndrome Based on Roma IV Diagnosis Criteria. People aged 18 to 50 years and if they are over 50 years old, colonoscopy should be screened to make sure there are no other diseases and malignancies. No malignancies (carcinoid and colorectal tumors), celiac disease, diverticulitis, gastrointestinal infections, hyper and hypothyroidism, lactose intolerance, IBD, and ischemic colitis No previous use of drugs, calcium channel blockers and antidepressants

**Exclusion criteria:**

Having a history of allergy to black seed compounds  
Dissatisfaction with attending the study Pregnancy

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is block randomization with block with sizes of two, four and six. We will use <https://www.sealedenvelope.com> for generating random sequences. This software will generate control and comparator groups and will generate unique codes for every participant. Participants will enroll according to the order of their entrance into the study. They will receive an opaque envelope that the unique code is on it and medicine is in it (concealment).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Study participants as patients in the two study groups, researchers and physicians under their supervision. are kept blind. For blinding patients, the drug and placebo are provided to patients in similar containers, which are only mentioned in the title of the research project and serial number. At the end of the study, the serial is converted to groups A and B in Excel software. Statistical analysis then determines which group of drugs or placebo

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jondishapur University of Medical Sciences

**Street address**

Azadegan St. (24 meters) Imam Khomeini Educational and Medical Center

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6193673111

**Approval date**

2022-01-09, 1400/10/19

**Ethics committee reference number**

IR.AJUMS.HGOLESTAN.REC.1400.154

**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**

severity of abdominal pain,

**Timepoint**

every two weeks for three consecutive months

**Method of measurement**

Irritable bowel syndrome severity questionnaire using Visual Analogue Scale

**2****Description**

severity of abdominal distension

**Timepoint**

every two weeks for three consecutive months

**Method of measurement**

Irritable bowel syndrome severity questionnaire using Visual Analogue Scale

**3****Description**

satisfaction with defecation habit

**Timepoint**

every two weeks for three consecutive months

**Method of measurement**

Irritable bowel syndrome severity questionnaire using Visual Analogue Scale

## Secondary outcomes

### 1

**Description**

Quality of life in patients with irritable bowel syndrome

**Timepoint**

At the beginning of the study and every month for three consecutive months.

**Method of measurement**

world health organization quality of life questioner (brief form)

## Intervention groups

### 1

**Description**

Intervention group: Patients with irritable bowel syndrome are taking 500 mg of black seed extract capsules every 12 hours during the study. Extraction and preparation of capsules is performed under the supervision of a pharmacist in Ahvaz Jundishapur School of Medical Sciences. The process of receiving black seed capsules is up to three months.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Patients with irritable bowel syndrome who take starch capsules as a placebo every 12 hours during the study. Extraction and preparation of capsules is done under the supervision of a refereeing specialist in Ahvaz Jundishapur School of Medical Sciences. The process of receiving black seed capsules is up to three months.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Imam Khomeini Hospital Ahwaz

**Full name of responsible person**

Pejman Alavi Nejad

**Street address**

Azadegan St., Imam Khomeini Medical Center

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drma59@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehrnoosh Zaker Kish

**Street address**

University City - Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences and Health Services - Ground Floor

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**Province**

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**Phone**

+98 61 3336 2414

**Email**

itc@ajums.ac.ir

**Web page address**

[http://behsan.ajums.ac.ir/webdocument/load.action?webdocument\\_code=1000&masterCode=33018099](http://behsan.ajums.ac.ir/webdocument/load.action?webdocument_code=1000&masterCode=33018099)

**Grant name**

RDC-0008

**Grant code / Reference number**

RDC-0008

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Nima Bakhtiarri

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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No 4, 4th east street, Kianpars, Ahvaz

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## Person responsible for scientific inquiries

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**Latest degree**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Nima Bakhtiari

**Position**

## 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

All data in the form of typed files and the names of distorted patients are presented north of the questionnaires.

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

Access period starts 6 months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

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

After obtaining a permission from the Vice Chancellor for Research of Ahvaz University

**From where data/document is obtainable**

Vice Chancellor for Research of Ahvaz University

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

By sending an email and a complete introduction and the reason for the need to receive information, if the request for documents is appropriate, it will be sent via email.

**Comments**