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

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)
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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
Ahwaz
Province
Khouzestan
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 Khomeyni Hospital Ahwaz

Full name of responsible person

Pejman Alavi Nejad

Street address

Azadegan St., Imam Khomeini Medical Center

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Khouzestan

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6193673111

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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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Ahwaz

Province

Khouzestan

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6135715794

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itc@ajums.ac.ir

Web page address

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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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
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