Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of black seed (Nigella sativa) on symptom severity in food-induced Irritable Bowel Syndrome.

Protocol summary

Study aim
the aim of this study was to evaluate the effect of nigella sativa on symptom severity in patients with food-induced irritable bowel syndrome IBS and to assess whether the improvement in IBS symptoms was maintained after discontinuation of the intervention.

Design
A prospective, single-arm interventional trial

Settings and conduct
Conducted at outpatient gastroenterology/internal medicine clinics in Mosul, Iraq on food-triggered IBS patients. After baseline assessment, patients took daily raw Nigella sativa seeds for 2 weeks, followed by a 2-week post-treatment evaluation. Open-label, unblinded, non-placebo-controlled study.

Participants/Inclusion and exclusion criteria
Patients between the ages of 18 and 52 who met the Rome IV diagnostic criteria for IBS and reported recurrent gastrointestinal symptoms that were commonly brought on by or made worse by specific meals were assessed for eligibility. The following were the exclusion criteria: Inflammatory bowel disease, coeliac disease, and gastrointestinal cancer are examples of organic gastrointestinal illnesses. severe long-term systemic problems (such uncontrolled cardiovascular disease, hepatic dysfunction, or renal failure). Sensitivities or allergy to Nigella sativa. lactation or pregnancy. Use of additional probiotics, herbal remedies, or typical IBS medicines (such as laxatives, antispasmodics, or antidiarrheals) within two weeks previous to baseline.

Intervention groups
Each participant received a pre-weighed box containing 30 g of raw, whole Nigella sativa seeds; this corresponds to a daily chewing of 2 g for 15 consecutive days.

Main outcome variables
The primary outcome variable is the change in the severity of gastrointestinal symptoms related to food-induced IBS (such as abdominal pain, bloating, and bowel habit changes)

General information

Reason for update

Acronym
NS - IBS

IRCT registration information
IRCT registration number: **IRCT20260806070557N1**
Registration date: **2026-08-29, 1405/06/07**
Registration timing: **retrospective**

Last update: **2026-08-29, 1405/06/07**
Update count: **0**

Registration date
2026-08-29, 1405/06/07

Registrant information

Name
Zahraa Younus

Name of organization / entity
The University of Al-Hamdaniya

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Iraq

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-04-01, 1405/01/12

Expected recruitment end date
2026-09-01, 1405/06/10

Actual recruitment start date
2026-04-01, 1405/01/12

Actual recruitment end date

2026-07-01, 1405/04/10

Trial completion date

2026-07-01, 1405/04/10

Scientific title

Evaluation of the effect of black seed (Nigella sativa) on symptom severity in food-induced Irritable Bowel Syndrome.

Public title

Effect of black seed (Nigella sativa) on symptom severity in food-induced Irritable Bowel Syndrome.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Adult aged 18 - 52 years All with food- induced irritable bowel syndrome who met the study eligibility criteria And agreed to participate in this study.

Exclusion criteria:

Inflammatory bowel disease coeliac disease, gastrointestinal cancer are examples of organic gastrointestinal illnesses severe long-term systemic problems (such uncontrolled cardiovascular disease, hepatic dysfunction, or renal failure). Sensitivities or allergy to Nigella sativa. lactation or pregnancy

Age

From **18 years** old to **52 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

not applicable

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Al- Hamdaniya - research ethics committee

Street address

Mosul - Bartella

City

Mosul - Bartella

Postal code

41001

Approval date

2026-03-29, 1405/01/09

Ethics committee reference number

UH.2026.003

Health conditions studied

1

Description of health condition studied

Food - induced irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Change in Irritable Bowel Syndrome (IBS) symptom severity score, including abdominal pain, bloating, and bowel habit frequency.

Timepoint

Measured at baseline (day 0), at the end of the 2-week active intervention period, and at the end of the 2-week post-intervention follow-up phase.

Method of measurement

Evaluated using a standardized IBS symptom severity questionnaire and self-reported patient symptom score logs.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intervention group: Each participant received a pre-weighed box containing 30 g of raw, whole Nigella sativa seeds (2 g daily for 15 days). Participants were instructed to chew the seeds thoroughly (0.67 g per meal) after main meals and swallow them with water.

Category

Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Private Outpatient Gastroenterology and Internal Medicine Clinics
Full name of responsible person
Zahraa Younus Saeed
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
self funding
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Zahraa Younus
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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
self funding
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Foreign
Category of foreign source of funding
Sponsor: country of origin
Country of origin
IQ
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
The University of Al-Hamdaniya
Full name of responsible person
Zahraa Younus Saeed
Position
assistant lecturer
Latest degree
Master
Other areas of specialty/work
Medical Pharmacy
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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
Undecided - It is not yet known if there will be 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 collected de-identified individual participant data, study protocol, statistical analysis plan, and informed consent form.
When the data will become available and for how long
Data will become available immediately upon publication of the study results and will remain available for 5 years.
To whom data/document is available
Qualified researchers and academicians upon reasonable request.
Under which criteria data/document could be used
For scientific research, meta-analysis, and validation of study findings only.
From where data/document is obtainable
Directly from the principal investigator via email.
What processes are involved for a request to access data/document
email to the principal investigator along with a brief research proposal. Responses will be provided within 2-4 weeks.
Comments
none