

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A Clinical Trial of the Effectiveness of Ajwain fruit extract on Inhibition of Irritable Bowel Syndrome (IBS) Symptoms and Its Comparison with Control Group

Protocol summary

Study aim

The Effect of Ajwain fruit extract in improving of Symptoms among Irritable Bowel Syndrome patients and Its Comparison with Control Group

Design

Clinical trial with control and parallel groups, single-blinded, randomized, in 2-3 phases, has been conducted on 80 patients. RAND function in Excel software has been used for randomization purposes

Settings and conduct

The Clinical trial has been conducted in 2-3 phase on 80 patients with Irritable Bowel Syndrome referring to gastroenterology clinic of Imam Khomeini Hospital. After signing the informed consent form, the participants completed life quality improvement scale both before and after treatment. At the end of treatment, the participants were required to score items on a 0-10 Likert Scale in terms of any observed improvement on the symptoms. The study is single-blinded and only the subjects have been put blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: Compliance with Irritable Bowel Syndrome (IBS) diagnostic criteria, the age range is 18-70 years. signing the informed consent form
Exclusion criteria: Pregnancy, lactation, the existence of underlying illnesses, allergy to Apiaceae plants family, dysfunctions in colonoscopy observations, consumption of IBS improvement medicines

Intervention groups

Intervention group: Oral prescription of a 100 mg capsule containing hydroalcoholic extract of Ajwain fruit and 400 mg of excipients, made in Pharmacognosy laboratory, implemented on 40 Irritable Bowel Syndrome (IBS) patients, three times a day for one-month
Control group: Oral prescription of a 400 mg capsule containing excipients of the main medicine, including lactose powder, corn starch, sodium lauryl sulfate and talc

powder, made in Pharmacognosy laboratory, implemented on 40 IBS patients, three times a day for one-month

Main outcome variables

Abdominal pain, Diarrhea, Constipation, Bloating, Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160306026938N8**

Registration date: **2021-07-22, 1400/04/31**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-22, 1400/04/31**

Update count: **0**

Registration date

2021-07-22, 1400/04/31

Registrant information

Name

Mahdi Vazirian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6412 1223

Email address

vazirian_m@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-10, 1400/04/19

Expected recruitment end date

2022-01-09, 1400/10/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical Trial of the Effectiveness of Ajwain fruit extract on Inhibition of Irritable Bowel Syndrome (IBS) Symptoms and Its Comparison with Control Group

Public title

The Effect of Ajwain fruit extract on Improvement of Irritable Bowel Syndrome (IBS) Symptoms

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adherence to diagnostic criteria of Irritable Bowel Syndrome (IBS) including recurrent abdominal pain at least three days in a month during past three months and beginning of symptoms at least from six months ago plus at least two conditions of three pain alleviation conditions after defecation, variations in number of defecation times and changes in stool consistency Age range of 18-70 years old Signing the informed consent

Exclusion criteria:

Being afflicted with any underlying disease pregnancy Being allergic to Apiaceae family plants Bowel dysfunctions including abnormal colonoscopy observations Lactation period Consumption of medications for improvement of irritable bowel syndrome symptoms

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization procedure has been implemented individually and using Excel's RAND function. To put it differently, the Excel software's RAND function generates randomized numbers (i.e. 0-1) and we consider (0-0.5) numbers as the Intervention group and the 0.5-1 numbers as the control group. Besides, the subjects weren't informed about receiving either treatment/placebo and the study was single blinded.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, only the participants were not informed

about receiving either treatment/placebo capsules. Thus, the study is a single-blinded one. The subjects in this study were not either relatives or friends, thus they couldn't compare the impacts of receiving placebo/treatment. In addition, the appearance of the capsules and their containing package was exactly similar in both Intervention/control group and is not differentiated. All the study subjects received a good deal of information regarding the research plan and have been presented to them. After being randomized through the use of statistical software package, treatment/placebo has been provided for them.

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 Medical Sciences

Street address

Islamic Azad University of Medical Sciences, Yakhchal Ave, Shariati Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2019-10-22, 1398/07/30

Ethics committee reference number

IR.IAU.PS.REC.1398.165

Health conditions studied**1****Description of health condition studied**

Irritable Bowel Syndrome (IBS)

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes**1****Description**

Abdominal pain

Timepoint

After intervention (one month after intervention)

Method of measurement

Scoring patients based on a 0-10 Likert Scale with regard to improvements in symptoms (0=no improvement; 10= complete improvement)

2

Description

Diarrhea

Timepoint

After intervention (one month after intervention)

Method of measurement

Scoring patients based on a 0-10 Likert Scale with regard to improvements in symptoms (0=no improvement; 10= complete improvement)

3

Description

Constipation

Timepoint

After intervention (one month after intervention)

Method of measurement

Scoring patients based on a 0-10 Likert Scale with regard to improvements in symptoms (0=no improvement; 10= complete improvement)

4

Description

Bloating

Timepoint

After intervention (one month after intervention)

Method of measurement

Scoring patients based on a 0-10 Likert Scale with regard to improvements in symptoms (0=no improvement; 10= complete improvement)

Secondary outcomes

1

Description

Quality of life score

Timepoint

Before intervention, 2 weeks after intervention, 4 weeks after study being initiated, 2 weeks after termination of the intervention

Method of measurement

Completing 34-item questionnaire of life quality among IBS patients (IBS_QOL34) by the patient himself

Intervention groups

1

Description

Intervention group: Oral prescription of a 100 mg capsule containing hydroalcoholic extract of Ajwain fruit, equal to 3 g of it and 400 mg auxiliary ingredients including lactose powder, corn starch, and talc powder and sodium

lauryl sulfate, made in Pharmacognosy laboratory of Tehran's University of Medical Science, administered on 40 Irritable bowel syndrome patients, three times a day (morning-noon-evening), for a one-month period

Category

Treatment - Drugs

2

Description

Control group: oral prescription of a capsule containing 400 mg of excipients of the main medicine including 350 mg lactose powder, 25 mg corn starch, 10 mg sodium lauryl sulfate and 15 mg talc powder, prepared in pharmacognosy laboratory of Tehran's University of Medical Science, administered in 40 Irritable bowel syndrome patients, three times a day (morning-noon-evening), for a one month period

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology clinics of Imam Khomeini hospital

Full name of responsible person

Dr. Najmeh Al Taha

Street address

Imam Khomeini Hospital, Keshavarz Blvd, Tehran, Iran

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Province

Tehran

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1419733141

Phone

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Email

imamhospital@tums.ac.ir

Web page address

<http://ikhc.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Doctor Mohammad Ali Sahraian

Street address

Central organization of Tehran university of medical sciences, corner of Ghods Ave., Keshavarz

City

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Tehran

Postal code
1417653761

Phone
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Email
rmo@tums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mahdi Vazirian

Position
PhD of Pharmacognosy

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Pharmacognosy Lab., Second Floor, New building,
Faculty of Pharmacy, In front of Oruji Alley, 16th Azar Ave., Enqelab Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mahdi Vazirian

Position
PhD of Pharmacognosy

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Person responsible for updating data

Contact

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Phone
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Email
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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
Yes - There is 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

Demographic specification of patients, would be published, except their names and address. Primary outcome of the patients would be published, too.

When the data will become available and for how long

Data would be available 6 months after publishing the results

To whom data/document is available

Data would be available for researchers in academic and scientific organisations

Under which criteria data/document could be used

Any type of usage of data is allowable, except using for manufacturing a product

From where data/document is obtainable

Sending an E. mail to mehdivazirian@gmail.com

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

After receiving E. mail, data would be sent within a week

Comments