Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of capsule containing dry extract of Trachyspermum ammi and Melissa officinalis in patients with irritable bowel syndrome (a clinical trial in phase 2B)

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 100 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

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

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: **IRCT20160306026938N10**
Registration date: **2022-07-11, 1401/04/20**
Registration timing: **prospective**

Last update: **2022-07-11, 1401/04/20**
Update count: **0**

Registration date

2022-07-11, 1401/04/20

Registrant information

Name
Mahdi Vazirian
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date
2023-02-19, 1401/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of capsule containing dry extract of Trachyspermum ammi and Melissa officinalis in patients with irritable bowel syndrome (a clinical trial in phase 2B)

Public title
The Effect of Ajwain fruit and Melissa 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
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
First, using the Random number generation plugin in excel software, a table of random numbers from 1 to 100 is prepared in a non-sequential and scattered manner, and the numbers are assigned to two intervention and control groups of 50 cases. The randomization process is performed by the methodology consultant and clinical researchers are not aware of the randomization process and will only be provided with random codes from 1 to 100.
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
Research Ethichs Committees of The Institute of Pharmaceutical Sciences- Tehran University Of Medica
Street address
16 Azar Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences, 2nd floor, Unit 1-219،
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2022-07-02, 1401/04/11
Ethics committee reference number
IR.TUMS.TIPS.REC.1401.203

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 100 mg of melissa officinalis 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. Mohammad Taher
Street address
Imam Khomeini Hospital, Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6693 9009
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 Ali Akbar Fotohi
Street address
Central organization of Tehran university of medical

sciences, corner of Ghods Ave., Keshavarz

City
Tehran

Province
Tehran

Postal code
1417653761

Phone
+98 21 8163 3639

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Email
research@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 buliding, 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

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Person responsible for updating data

Contact

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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
ny 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