

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of Ajwain fruit extract efficacy in management of symptoms of patients with Irritable Bowel Syndrome (IBS): A Case Series Study

Protocol summary

Summary

Project goal: investigation of Ajwain extract efficacy in relieving annoying symptoms of patients with IBS. Design of study: non-Randomized, non-blind, without placebo control, single-centre, phase 0 trial. Study group: patients with irritable bowel syndrome (IBS). Major inclusion criteria: to be in accordance with the Rome II criteria. Major exclusion criteria: presence of concurrent disease and organ dysfunction, pregnancy and breastfeeding, showing evidence of allergy to the plant. Sample size: 60 patients. Study intervention/interventions: intake of edible capsule containing Ajwain fruit extract, 15 minutes before each meal. Intervention period: 4 weeks. Primary outcome or outcomes of the study: abdominal pain; severity of nausea; painful defecation; presence of mucus in stool; changes in stool consistency; stool frequency and pain with defecation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030626938N1**

Registration date: **2016-03-27, 1395/01/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-27, 1395/01/08

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

Tehran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Ajwain fruit extract efficacy in management of symptoms of patients with Irritable Bowel Syndrome (IBS): A Case Series Study

Public title

Effect of Ajwain fruit extract in improving irritable bowel syndrome (IBS) symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: based on ROME II criteria and presence of abdominal pains, at least for 12 consecutive or inconsecutive weeks, which includes at least one of the 3 following criteria: 1- relief with defecation; 2- changes in frequency of stool; 3- changes in stool consistency .

Exclusion criteria: concurrent disease (including chronic pulmonary disease, asthma, diabetes, thyroid disease or mental disease); pregnancy or breastfeeding and presence of sensitivity or allergic reactions to

umbelliferae family; lack of patient cooperation in the treatment process.

Age

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

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **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

Assessment of medication effect is based on patients symptoms before, and 2 and 4 weeks after treatment initiation and also 2 and 4 weeks after treatment termination.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qods street corner, Keshavarz Blvd, Tehran, Iran.

City

Tehran

Postal code

Approval date

2016-03-05, 1394/12/15

Ethics committee reference number

IR.TUMS.REC.1394.2147

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrome (IBS)

ICD-10 code

K58

ICD-10 code description

Irritable colon

Primary outcomes

1

Description

Abdominal pain

Timepoint

Before intervention, 2 weeks after intervention, 4 weeks after intervention, 2 weeks after cessation of intervention and 4 weeks after cessation of intervention

Method of measurement

Severity of pain reported by the patient (Mild, Moderate, Severe) in questionnaire

2

Description

Severity of Nausea

Timepoint

Before intervention, 2 weeks after intervention, 4 weeks after intervention, 2 weeks after cessation of intervention and 4 weeks after cessation of intervention

Method of measurement

Severity of nausea reported by the patient (Mild, Moderate, Severe) in questionnaire

3

Description

Painful defecation

Timepoint

Before intervention, 2 weeks after intervention, 4 weeks after intervention, 2 weeks after cessation of intervention and 4 weeks after cessation of intervention

Method of measurement

Report of the patient (Yes/No) in questionnaire

4

Description

Presence of mucus in feces

Timepoint

Before intervention, 2 weeks after intervention, 4 weeks after intervention, 2 weeks after cessation of intervention and 4 weeks after cessation of intervention

Method of measurement

Report of the patient (Yes/No) in questionnaire

5

Description

Changes in feces consistency

Timepoint

Before intervention, 2 weeks after intervention, 4 weeks after intervention, 2 weeks after cessation of intervention and 4 weeks after cessation of intervention

Method of measurement

Report of the patient (Changed/Unchanged) in questionnaire

6

Description

Change in frequency of stool

Timepoint
Before intervention, 2 weeks after intervention, 4 weeks after intervention, 2 weeks after cessation of intervention and 4 weeks after cessation of intervention

Method of measurement
Report of frequency of defecation by the patient in questionnaire

Secondary outcomes

1

Description
Pain with defecation

Timepoint
Before intervention, 2 weeks after intervention, 4 weeks after intervention, 2 weeks after cessation of intervention and 4 weeks after cessation of intervention

Method of measurement
Report of the patient (Mild, Moderate, Severe) in questionnaire

Intervention groups

1

Description
Prescription of edible capsule containing hydroalcoholic extract of Ajwain fruit, based on 3 grams of the fruit, 3 times a day for 4 consecutive weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Traditional Medicine, Tehran University of Medical Sciences

Full name of responsible person
Dr. Mehrdad Karimi

Street address
Faculty of Traditional Medicine, Tehran University of Medical Sciences, Giti alley, Vafamanesh Ave., Heravi Sq., Pasdaran Ave.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mahdi Vazirian

Street address

Faculty of Pharmacy, In front of Oruji Alley, 16th Azar Ave., Enqelab Ave.

City
Tehran

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
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

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

Other areas of specialty/work

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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Web page address

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Person responsible for updating data

Contact

Name of organization / entity
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City

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty