

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Randomised Clinical Trial: Enteric-coated Anise-oil capsules vs. placebo & active controlled in Irritable Bowel Syndrome - A 4 week double-blind study with 2 weeks follow-up

Protocol summary

Summary

The purpose of this study is to assess the efficacy of Enteric-coated Anise-oil capsules comparing with placebo and Colpermin® for treatment of IBS patients. 120 patients with confirmed IBS with non-response criteria selected. In this double blind pilot study, the patients and researchers will be blinded about Receiving Drug, Placebo and Active allocation. Patients will be randomized into group A (Anise-oil EC Capsule 187 mg daily, for 4 weeks), group B (placebo Capsule once daily, for 4 weeks) and group B (Colpermin® Capsule once daily, for 4 weeks). At the end of therapy (4 weeks) and at baseline (first), 2 weeks after receiving drug, placebo and Colpermin® IBS load, will be evaluated and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205069651N1**

Registration date: **2015-02-03, 1393/11/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-03, 1393/11/14

Registrant information

Name

Maryam Mosaffa-Jahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3208 4030

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomised Clinical Trial: Enteric-coated Anise-oil capsules vs. placebo & active controlled in Irritable Bowel Syndrome - A 4 week double-blind study with 2 weeks follow-up

Public title

The Effect of Anise-oil capsules on IBS Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Meeting the Rome III Modular Questionnaire; Patients with 50 years were required to have a colonoscopy performed within the previous 5 years; Patients under the age of 50 years were required to have a sigmoidoscopy performed Exclusion criteria: Unable or unwilling patients to use an acceptable method of birth control; Pregnant or nursing females; Previous gastrointestinal or abdominal surgery (except for common causes unrelated to IBS); Organic disorder of the large or small bowel (e.g. ulcerative colitis, Crohn's

disease); Mechanical obstruction; Unexplained significant weight loss or rectal bleeding; Diagnosis of any medical condition associated with constipation (other than IBS); Cancer; Abnormal laboratory tests; Abuse of alcohol or drugs

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee, Shiraz University of Medical Sciences

Street address

zand street, Shiraz University of Medical Sciences, 7th floor

City

Shiraz

Postal code**Approval date**

2013-03-13, 1391/12/23

Ethics committee reference number

CT-91-6460

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

Non- Response IBS Patients

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

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

Quality of Life (QOL), pain, flatulence, diarrhea, constipation, reflux, headache and tiredness

Timepoint

Baseline

Method of measurement

(IBS-QOL) questionnaire and 10-point visual scale ranging

Secondary outcomes**1****Description**

Change in Quality of Life (QOL), pain, flatulence, diarrhea, constipation, reflux, headache and tiredness at end of treatment

Timepoint

End of Follow Up (6 weeks after starting intervention)

Method of measurement

(IBS-QOL) questionnaire and 10-point visual scale ranging

Intervention groups**1****Description**

Intervention Group: Anise-oil EC Capsule, One Cap (187mg)/day for 4 weeks. Patients will be followed at Baseline, 4 and 6 Weeks after Starting Intervention.

Category

Treatment - Drugs

2**Description**

Placebo Group: One Placebo Capsule/Day for 4 Weeks. Patients will be followed at Baseline, 4 and 6 Weeks after Starting Intervention.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Motahari Clinic, Shiraz University of Medical Sciences, Zand Avenue, Shiraz, Iran.

Full name of responsible person

Dr. Maryam Mosaffa-Jahromi

Street address**City**

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Kamran Bagheri Lankarani

Street address

Health Policy Research Center, School of Medicine,
Zand Avenue, Shiraz, Iran

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Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Health Policy Research Center

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Dr. Maryam Mosaffa-Jahromi

Position

Pharm.D, PhD Student in Traditional Pharmacy

Other areas of specialty/work

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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