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)

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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 staring 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. Paients 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. Paients 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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Kamran Bagheri Lankarani
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Health Policy Research Center, School of Medicine, Zand Avenue, Shiraz, Iran
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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
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

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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