

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effect of Peppermint (*Mentha Piperita*) with placebo on severity of symptoms in patients with irritable bowel syndrome

Protocol summary

Study aim

Determination of the effect of mint extract on the severity of symptoms in patients with irritable bowel syndrome

Design

A randomized controlled trial clinical trial with parallel, double-blind, randomized groups.

Settings and conduct

This study is carried out at the Gastroenterology Clinic of Amirmomenin Hospital. Samples will be selected from patients with irritable bowel syndrome. Then they are randomly divided into two groups of intervention and control. The intervention group, in addition to the usual treatments, received 10 drops of Barijan Mint extract twice daily for one month after lunch and dinner. The control group, in addition to the usual treatments, received 10 placebo drops twice daily for lunch and dinner for one month. The study is a double blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, ages 18 to 65, Gastrointestinal intestinal syndrome is diagnosed by a gastroenterologist. Exclusion criteria: record of any major bowel surgery, metabolic or other diseases, taking corticosteroid drugs, taking of steroidal anti-inflammatory drugs.

Intervention groups

Group 1 (intervention): in addition to the medications prescribed by the physician, the amount of 10 drops of mint extract of Barij Essence Company is given twice a day after lunch and dinner for one month. Group 2 (placebo): in addition to the medications prescribed by the physician, are given placebo (colored water), the amount of 10 drops is given twice a day after lunch and dinner for one month.

Main outcome variables

Severity of symptoms of irritable bowel syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130731014229N10**

Registration date: **2019-10-31, 1398/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-31, 1398/08/09**

Update count: **0**

Registration date

2019-10-31, 1398/08/09

Registrant information

Name

Hadi Jafari manesh

Name of organization / entity

Arak University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3503

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jafarimanesh@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Peppermint (Mentha Piperita) with placebo on severity of symptoms in patients with irritable bowel syndrome

Public title

Effect of Peppermint (Mentha Piperita) on severity of symptoms in patients with irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The desire to participate in the study Aged 18 to 65
Gastrointestinal intestinal syndrome is diagnosed by a gastroenterologist

Exclusion criteria:

history of any major bowel surgery metabolic diseases or other diseases taking corticosteroids taking Non-steroidal anti-inflammatory drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are randomly assigned to quadruple blocks A, A, B, B in random groups. So that 8 blocks of 4 letters A and B are made up. Then a block is randomly selected. A indicates sample placement in intervention group and B indicates sample placement in control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and data analyzer do not know which groups are located. The samples in the intervention and control group did not know whether they received the placebo or the main drug. The statistician will receive questionnaires as anonymously and in form A and B, and he does not know which are intervention and control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Basij Sq.

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2019-05-05, 1398/02/15

Ethics committee reference number

IR.ARAKMU.REC.1398.083

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Severity of symptoms of irritable bowel syndrome

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Gastrointestinal Symptom Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in addition to the medications prescribed by the physician, the amount of 10 drops of mint extract of Barij Essence Company is given twice a day after lunch and dinner for one month.

Category

Treatment - Drugs

2

Description

Control group: in addition to the medications prescribed by the physician, are given placebo (colored water), the amount of 10 drops is given twice a day after lunch and dinner for one month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Clinic of Amiralmomenin Hospital.

Full name of responsible person

Hadi Jafarianesh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadega

Street address

Deputy of Research and Technology, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, 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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Hadi Jafarianesh

Position

Faculty

Latest degree

Master

Other areas of specialty/work

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

Undecided - It is not yet known if there will be 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