

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparision of effectiveness of Teucrium polium and placebo on Total IBS symptom Score, abdominal pain severity, bloating and spasm in patients with Irritable Bowel Syndrome

Protocol summary

Summary

General objective: Determination of the effect of Teucrium polium capsule on Total IBS Symptom Score, abdominal pain severity, spasm, and bloating in patients with IBS Design of study: randomized, double blind, placebo controlled trial. Method of study: A) the study population: the patients with IBS have admitted in Ziaei Hospital would be passed inclusion criteria can participate in study. This patients will be divided randomized in two group. the first Group will be used Teucrium polium capsule for one month, the second group will be used placebo (starch) capsule for one month. Before and after intervention Total IBS Symptom Score, abdominal pain severity, spasm, bloating and LFT will be recorded, analysed at the end of study. Inclusion criteria: age between 18 - 65 years old; receiving written informed consent from patients; having IBS. Exclusion criteria: individuals will not to continue the study; any chronic diseases (cardiac disease, prostate hyperplasia, kidney failure, liver disease, glaucoma); having allergy to herbal products (specially including Teucrium polium); any use of herbal medications in last 3 months; pregnancy. B) Sample size: 70 (will be divided randomized in two 35 patients group). C) intervention in study: Teucrium capsule & placebo capsule D) duration of intervention: one month E) the primary outcome: reduce of severity of abdominal pain & Total IBS Symptom Score after intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082529327N4**
Registration date: **2017-10-23, 1396/08/01**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-23, 1396/08/01

Registrant information

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Ramin Abrishami

Name of organization / entity

Islamic Azad University, Pharmaceutical sciences branch

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Researcher

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of effectiveness of Teucrium polium and placebo on Total IBS symptom Score, abdominal pain severity, bloating and spasm in patients with Irritable Bowel Syndrome

Public title

The effect of Teucrium polium on Irritable Bowel Syndrome symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 - 65 years old; receiving written informed consent from patients; having IBS. Exclusion criteria: individuals will not to continue the study; any chronic diseases (cardiac disease, prostate hyperplasia, kidney failure, liver disease, glaucoma); having allergy to herbal products (specially including Teucrium polium); any use of herbal medications in last 3 months; pregnancy.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

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 of Islamic Azad University of Pharmaceutical Sciences

Street address

#99, The First of Yakhchal Ave., Gholhak, Shariati St.

City

Tehran

Postal code

19395-6466

Approval date

2017-05-08, 1396/02/18

Ethics committee reference number

IR.IAU.PS.REC.1397.87

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome

ICD-10 code

K58 , K58.

ICD-10 code description

Irritable bowel syndrome, Irritable bowel syndrome with diarrhoea, Irritable bowel syndrome without diarrhoea

Primary outcomes

1

Description

Total IBS symptom Score

Timepoint

before intervention, one month after intervention

Method of measurement

questionnaire

2

Description

abdominal pain severity

Timepoint

before intervention, one month after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

spasm

Timepoint

before intervention, one month after intervention

Method of measurement

questionnaire

2

Description

bloating

Timepoint

before intervention, one month after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

intervention group: in people with inclusion criteria to be given 250 mg oral Teucrium polium capsule , 4 times daily , for one month.

Category

Treatment - Drugs

2

Description

control group: in people with inclusion criteria to be given oral placebo capsule (contain 250 mg of Starch powder) 4 times daily for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ziaeeian Hospital

Full name of responsible person

Roghayeh Mahdi

Street address

Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Roghayeh Mahdi

Full name of responsible person

Roghayeh Mahdi

Street address

Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Roghayeh Mahdi

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

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Full name of responsible person

Ramin Abrishami

Position

Assistant professor

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