Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Iranian traditional medicine on the basis of ARTEMISIA ABSINTHIUM on the improvement of symptoms of irritable bowel syndrome patients with constipation prevalence

Protocol summary

Summary

The present study is a double-blind, randomized clinical trial that investigated the effect of Iranian traditional medicine on clinical signs and constipation in patients with constipated IBS. 70 patients with inclusion criteria were selected and randomly assigned to two groups of 35 intervention They are divided by medicine or placebo. Drugs and placebo are given as syrups three times a day, each 10 cc every 6 weeks for patients. To evaluate the symptoms, the IBS-SSS severity questionnaire (5 questions) and the severity of depression and anxiety (HADS) of 14 questions and Bristrol Stool Form Scale for stool consistency were used. The questionnaire is completed at the beginning of the study and after the end of the intervention, 6 and 4 weeks after the end of the treatment, the 10th week by the patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061034446N1**
Registration date: **2017-07-25, 1396/05/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-25, 1396/05/03

Registrant information

Name

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Name of organization / entity

Mashhad Faculty of Traditional and Complementary Medicine

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology, Mashhad University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Iranian traditional medicine on the basis of ARTEMISIA ABSINTHIUM on the improvement of symptoms of irritable bowel syndrome patients with constipation prevalence

Public title

The effect of Iranian traditional medicine on IBS disease

Purpose

Treatment

Inclusion/Exclusion criteria

The criteria for entry are based on the diagnostic criteria of IBS, namely, ROME IV, which is as follows: (Recurrent abdominal pain at least one day a week in the last three months, with at least two of the following three characteristics: related to bowel movements - with a change in the frequency of bowel movements -

accompanied by changes in the shape of the stool These symptoms start at least six months before the diagnosis.); constipation based on Bristrol Stool Form Scale; age between 18-50 years old; not having severe mental and behavioral disorders; no history of organic bowel disease; lack of pregnancy or breastfeeding; lack of drug addiction; no history of any major bowel surgery; serious and malignant systemic disease; the inability to use interfering chemical and vegetable medications with treatment. Exit criteria: pregnancy during the study; in the event of drug complications or other medical problems; unwillingness to continue treatment.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

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 Mashhad University of Medical Sciences

Street address
University of Science and Technology, Faculty of Science and Technology, Mashhad University of Medical Sciences Mashhad Khorasan Razavi Iran

City
Mashhad

Postal code

Approval date
2017-06-06, 1396/03/16

Ethics committee reference number
IR.MUMS.REC.1396.48

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome with constipation prevalence

ICD-10 code
K58

ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Severity of disease, stool consistency,

Timepoint
At the beginning of the study and before starting treatment

Method of measurement
Illness severity questionnaire - IBS-SSS and Bristrol Stool Form Scale

Secondary outcomes

1

Description
anxiety and depression

Timepoint
6 weeks after starting treatment and 4 weeks after treatment

Method of measurement
questionnaire severity of depression and anxiety-HADS-

Intervention groups

1

Description
Control group: A similar medicinal product to the non-herbicide group was given as placebo for 6 weeks three times a day, each time 10 cc were given to the patients and the clinical manifestations of the patients at the beginning of the study and the week 6 treatments and 4 weeks after treatment discontinuation we do

Category
Placebo

2

Description
Intervention group: Syrup containing a certain amount of herbs of ARTEMISIA ABSINTHIUM, CUSCUTA EPITHYMUM, CASSIA FISTULA, ECHIUM AMOENIUM, MELLISA OFFICINALLIS weighing 10 cc three times a day for 6 weeks will be given at the start of the study and 6 weeks of treatment and 4 weeks after the follow-up treatment

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology clinic of Ghaem Hospital
Full name of responsible person
Hamide Khorram Pajooh
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Gastroenterology clinic, Ghaem Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Deputy of Science and Technology, Mashhad University of Medical Sciences, Daneshgah St.
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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
Deputy of Research and Technology, Mashhad 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
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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