

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 Bristol 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

Hamide Khorram Pajooh

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 Bristol 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 Bristol 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 EPITHYMIUM, CASSIA FISTULA, ECHIUUM 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 Pajooch

Street address

Gastroenterology clinic, Ghaem Hospital

City

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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

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamide Khorram Pajooch

Position

Assistant Professor of Traditional Iranian Medicine

Other areas of specialty/work

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Full name of responsible person

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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