

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The effect of combination of Descurainia Sophia and Deracocephalum syrup on clinical symptoms and quality of life in patients with irritable bowel syndrome with predominant constipation

Protocol summary

Study aim

evaluation of effect of Dracocephalum and Descurainia sophia syrup on clinical symptoms and quality of life in patients with irritable bowel syndrome with constipation

Design

This study is a randomized, double-blind clinical trial with parallel groups and a control group that will be performed with the participation of 90 patients ; Patients will be divided into intervention and control groups by block randomization

Settings and conduct

The samples will be selected from gastroenterology clinics of Emam Reza hospital of Tabriz.patients will be placed in one of the two groups. Patients in intervention group will take 10cc of Dracocephalum and Descurainia sophia syrup daily for 1month and control group will receive 10cc of placebo syrup daily for 1month.patients symptom will be assessed by Patient Assessment of Constipation-Symptom (PAC-SYM) questionnaire and Quality of life will be assessed by the quality of life questionnaire.researchers and patients and data analyzer will be blind in this study.

Participants/Inclusion and exclusion criteria

patients will be selected from the person referred to Gastroenterology clinics whom diagnosed as IBS patients according to ROME IV criteria with constipation.Inclusion criteria include: Age at 18-75 year, and willingness to participate and having normal colonoscopy.exclusion criteria include:history of drug reaction;pregnancy and lactation, having ulcerative colitis or crohn disease ,pathologic findings in colonoscopy

Intervention groups

This study will be a randomized, double -blind clinical trial with parallel groups; 90people will be randomly divided into two groups. Patients in the intervention group will take combination of Dracocephalum and Descurainia sophia syrup and control group will receive

placebo syrup.

Main outcome variables

Quality of life of IBS patients ;stool stiffness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220104053626N5**

Registration date: **2023-01-24, 1401/11/04**

Registration timing: **prospective**

Last update: **2023-01-24, 1401/11/04**

Update count: **0**

Registration date

2023-01-24, 1401/11/04

Registrant information

Name

Masood Dinevari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combination of Descurainia Sophia and Deracocephalum syrup on clinical symptoms and quality of life in patients with irritable bowel syndrome with predominant constipation

Public title

The effect of combination of Descurainia Sophia and Deracocephalum syrup on patients with irritable bowel syndrome with constipation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

having IBS according to ROME IV criteria age above 18 having normal colonoscopy within 5 years willing to participate

Exclusion criteria:

pregnancy and lactation any history of drug reaction celiac disease recent use of probiotics,laxatives,antibiotics and anti inflammatory drugs such as NSAID and corticosteroides. history of inflammatory bowel disease(ulcerative colitis and crohn disease) any pathologic findings in colonoscopy

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

From the patients who volunteered to participate in the study, 90 persons will be selected by simple random sampling. Randomization method:block Randomization unit : Individual Randomization layers: In each block, people will be matched based on age and gender. Random Allocation software: Random Allocation software How to create a random sequence: Using Random Allocation software Hide: The random sequence created is kept in a safe place and is done by an independent person who is not involved in the experiment during the study. Random allocation of hidden individuals, patients and researchers will not be aware of it.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study in which the researcher

of this study and the patients participating in the study will be unaware of the type of syrup received. Syrups will be provided to patients by another person who has no role in completing the questionnaire and following patients. Patients will also be informed of the existence of two types of syrups (placebo syrup and combination of Descurainia Sophia and Deracocephalum syrup) when obtaining consent, but will be unaware of which study groups they will be included in. Descurainia Sophia and Deracocephalum syrups are similar in appearance color, and size to placebo syrups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Ethics committee,vice chancellor for research, Faculty of medicine, Tabriz University of Medical Sciences, Golgasht st, Tabriz, Iran

City

Tabriz

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East Azarbaijan

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5163996889

Approval date

2022-12-26, 1401/10/05

Ethics committee reference number

IR.TBZMED.REC.1401.901

Health conditions studied**1****Description of health condition studied**

irritable bowel syndrome

ICD-10 code

K58.9

ICD-10 code description

Irritable bowel syndrome without diarrhea

Primary outcomes**1****Description**

Patients quality of life

Timepoint

Before and after the intervention

Method of measurement

The quality of life questionnaire for patients with irritable bowel syndrome

2

Description

Stool stiffness

Timepoint

before and after intervention

Method of measurement

Patient Assessment of Constipation-Symptom(PAC-SYM) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will take 10cc of Descurainia sophia and Dracocephalum syrup(manufactured by Tabriz Traditional Medicine Center) daily for one month.

Category

Treatment - Drugs

2

Description

Control group: patients in the control group will take 10cc of placebo syrup (manufactured by Tabriz Traditional Medicine Center)daily for one month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Masood Faghieh Dinevari

Street address

Emam reza hospital, Golgasht st,Tabriz.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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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

Tabriz University of Medical Sciences

Proportion provided by this source

50

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

Tabriz University of Medical Sciences

Full name of responsible person

Masood faghieh Dinevari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable