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 citeria 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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dinvarim@tbzmed.ac.ir

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 Univarsity of Medical Sciences,Golgasht st,Tabriz,Iran
City
Tabriz
Province
East Azarbaijan
Postal code
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 Faghih Dinevari

Street address

Emam reza hospital, Golgast 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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Vice chancellor for Research,Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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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 faghih Dinevari

Position

Assisstant 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