Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Pistacia atlantica oleoresin on clinical symptoms of the patients with Irritable bowel syndrome with constipation predominance

Protocol summary

Study aim

Evaluation of the effect of Pistacia atlantica oleoresin on clinical symptoms of the patients with Irritable bowel syndrome with constipation predominance

Design

placebo-controlled, double-blind, randomized, phase 3 on 70 patients, randomization is performed by permuted block randomization method, and drugs will be randomly allocated to patients

Settings and conduct

A total of 70 patients referred to Ayatollah Rouhani Hospital, Omid Clinic, and Traditional Medicine Health Center of Babol University of Medical Sciences, first complete the (IBS-SSS) and (IBS-QOL) questionnaires. In the intervention group, capsules containing P.atlantica are given twice daily for 6 consecutive weeks, and in the control group, capsules containing starch are given. The capsule consumption by each volunteer is monitored weekly, patients are treated for 6 weeks. Then refer and the relevant questionnaires are completed. Finally, the IBS-SSS and IBS-QOL are completed for patients four weeks after the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion: Patients diagnosed with IBS, age over 18, patient informed consent exclusion: Pregnancy/lactation, history of gastrointestinal surgery, inability to swallow capsules, herb allergies, heart/liver/kidney diseases, use of psychiatric drugs, use of P.atlantica in the past month, use of prebiotic/probiotics, antibiotics, laxative, alcohol, NSAID, drugs that alter the movement of the gastrointestinal tract, patients with malignancies, smoking

Intervention groups

The group receiving P.atlantica and the group receiving placebo

Main outcome variables

Primary : Change in the severity of irritable bowel syndrome based on the total score of the IBS-SSS scale Secondary : Quality of life change based on changing the total score of the IBS-QOL quality of life questionnaire Symptomatic changes in the IBS-SSS Irritable Bowel Syndrome Severity Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211214053405N1**
Registration date: **2022-01-01, 1400/10/11**
Registration timing: **prospective**

Last update: **2022-01-01, 1400/10/11**
Update count: **0**

Registration date

2022-01-01, 1400/10/11

Registrant information

Name

Amir Adibifard

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Pistacia atlantica oleoresin on clinical symptoms of the patients with Irritable bowel syndrome with constipation predominance

Public title
Evaluation of the effect of Pistacia atlantica oleoresin on Irritable bowel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient has not been treated with Pistacia atlantica oleoresin for the past month Patients with IBS whose type of disease has been confirmed by a complete medical examination. The patient signs a written consent Age over 18 years
Exclusion criteria:
Pregnant or lactating women Patients with malignancies or other chronic gastrointestinal diseases such as inflammatory bowel disease and celiac disease History of major gastrointestinal surgery (including Billroth surgery, ostomy, and any resection in any part of the gastrointestinal tract). Inability to swallow capsules People taking psychotherapy drugs Patients at a serious health risk, including severe heart, liver or kidney disease Patients with severe plant allergies Regular use of drugs that change the movement of the gastrointestinal tract such as metoclopramide, cisapride, drugs, diphenoxylate, etc. Regular use of laxatives Follow the diet plans with daily and regular intake of prebiotic/probiotic compounds Taking antibiotics The patient has been treated with Pistacia atlantica for the past month Cigarette smoking, alcohol usage NSAID usage
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done by permuted block randomization method and concealment is done. Patients are divided into two groups using the above method. Six of the four combinations of intervention groups A and B are determined AABB ABAB ABBA ABBA BBAA BABA BAAB and randomly select each of the above combinations and those who agree to participate in the study are placed in study groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, blinding will be double-blind. In this way, patients will not be aware of their position in the two groups and the drug and placebo will be prepared in identical forms (in terms of color, smell, and taste) in the form of capsules for both groups. P. atlantica oleoresin capsules are delivered to the intervention group, and placebo capsules containing starch are delivered to the control group. The researcher responsible for collecting the initial data and the outcomes will not be aware of the type of drug the patients are taking.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
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Babol ganjafrooz st
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Approval date
2021-10-06, 1400/07/14
Ethics committee reference number
IR.MUBABOL.REC.1400.239

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
Change in the severity of irritable bowel syndrome based on the total score of the IBS-SSS scale
Timepoint
The beginning of the study and the sixth week of the intervention and one month after the intervention
Method of measurement
Irritable Bowel Syndrome Severity Questionnaire (IBS-SSS)

Secondary outcomes

1

Description
quality of life based on change in total score of IBS-QOL quality of life questionnaire, change in symptoms of IBS-SSS Irritable Bowel Syndrome Scale
Timepoint
Initially study and the sixth week of intervention and one month after intervention
Method of measurement
Quality of Life Questionnaire for Patients with Irritable Bowel Syndrome (IBS-QOL)

2

Description
The severity of symptoms subsets of the IBS-SSS Irritable Bowel Syndrome questionnaire
Timepoint
Initially study and the sixth week of intervention and one month after intervention
Method of measurement
IBS-SSS questionnaire

Intervention groups

1

Description
Intervention group: P.atlantica oleoresin capsule (Saqez) and placebo are prepared by a pharmacist in the traditional pharmacy laboratory of the Faculty of Traditional Medicine of Babol University of Medical Sciences. oleoresin is prepared in capsules weighing 500 mg. Tests are performed to control microbial and chemical analysis of the essential oil. Both drug and placebo are packaged in similar containers. The drug is taken twice a day for six weeks.
Category
Treatment - Drugs

2

Description
Control group: The placebo capsule is prepared by a pharmacist in the traditional pharmacy laboratory of the Faculty of Traditional Medicine of Babol University of Medical Sciences. The placebo capsules are filled with cornstarch (weighing 500 mg). Tests to control microbial contamination are performed. Both products are packaged in similar containers. To match the odor, placebo capsules are placed for a while in an area adjacent to P.atlantica essential oil. The placebo is taken twice a day for six weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Babol University of Medical Sciences

Proportion provided by this source
100

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
Babol University of Medical Sciences

Full name of responsible person
Amir Adibifard

Position
ph.D Student

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available