

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)

Phone

+98 21 7790 8363

Email address

a.adibifard@mubabol.ac.ir

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, diphenoxyllate, 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

Street address

Babol ganjafrooz st

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

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 (Saquez) 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

Amir Adibifard

Street address

Ganjafrooz st

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 2229 5915

Fax

+98 11 1229 0181

Email

Amiradibifard@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr.Reza ghadimi

Street address

Ganjafrooz st

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 2229 5915

Fax

+98 11 1229 0181

Email

rezaghadimi@yahoo.com

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
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Ganjafrooz st
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 21 7790 8363
Email
Amiradibifard@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Narjes Gorji
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Ganjafrooz
City
Babol

Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 3219 4730
Fax
+98 11 1229 0181
Email
N.gorji@mubabol.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Amir Adibifard
Position
ph.D student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Ganjafrooz st
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 21 7790 8363
Email
amiradibifard@yahoo.com

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