

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The Effect of Pomegranate peel extract on clinical symptoms ,stool calprotectin level and quality of life in patients with diarrhea-dominant irritable bowel syndrome : A double-blind randomized placebo-controlled clinical trial

Protocol summary

Study aim

The effect of pomegranate peel extract on clinical symptoms ,quality of life and stool calprotectin level of patients with diarrhea dominant irritable bowel syndrome

Design

This study was performed as a double-blind randomized clinical trial with a control group, with parallel groups, phase 3 on 62 patients. The two intervention groups and the control group were randomly by graphed software and the sample size using g-power software, There are 31 people in each group.

Settings and conduct

Sampling and diagnosis will be performed in gastrointestinal clinics affiliated to Tabriz University of Medical Sciences. In this study, for blinding, drug and placebo were prepared in similar packages and one of the colleagues will use labels A and B for differentiation. And none of the researchers as well as patients will be aware of the contents of A and B until the end of statistical analysis. patients, researchers, outcome evaluators, and data analysts will be blind.

Participants/Inclusion and exclusion criteria

1. Irritable bowel syndrome with predominant manifestation of diarrhea 2. Age over 18 3. Normal colonoscopy during the last 5 years 4. Stool calprotectin level above 50

Intervention groups

1. Intervention group: A group of patients with irritable bowel syndrome (IBS) with a predominant manifestation of diarrhea were randomly assigned to receive a drug package for two months. 2. Control group: A group of patients with IBS with a predominant manifestation of diarrhea were randomly assigned to receive a placebo package for two months.

Main outcome variables

1. Clinical symptoms before and after the intervention,

which are scored by a questionnaire and will be a small criterion. 2. Fecal calprotectin levels before and after the intervention 3. Quality of life of patients before and after the intervention (scored by the Quality of Life Questionnaire for patients with irritable bowel syndrome)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210423051046N1**

Registration date: **2022-01-05, 1400/10/15**

Registration timing: **retrospective**

Last update: **2022-01-05, 1400/10/15**

Update count: **0**

Registration date

2022-01-05, 1400/10/15

Registrant information

Name

Fateme Javanali Azar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3320 1463

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Pomegranate peel extract on clinical symptoms ,stool calprotectin level and quality of life in patients with diarrhea-dominant irritable bowel syndrome : A double-blind randomized placebo-controlled clinical trial

Public title

The effect of pomegranate peels extract on clinical symptoms of patients with irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Irritable bowel syndrome patients with diarrhea dominant symptom

Exclusion criteria:**Age**From **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **62****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will be done using Graph pad software, so that the groups will be marked with two letters A and B. And then the software will assign each person to one of the groups A and B. This list will be prepared by one of the researchers who has no role in the other parts of the study and will be hidden from the others until the end of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, medicine and placebo are prepared in similar packages and one of the colleagues will use labels A and B for differentiation and none of the researchers as well as patients will be aware of the contents of A and B until the end of statistical analysis.

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 science

Street address

Deputy of Research and Technology, 3th floor, Central building NO. 2, Tabriz University of Medical Sciences, Golgasht St, Tabriz, Iran

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Approval date

2020-10-05, 1399/07/14

Ethics committee reference number

IR.TBZMED.REC.1399.686

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

Irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

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

Score of clinical symptoms in first questionnaire

Timepoint

Before the intervention and 2 months after the beginning of intervention

Method of measurement

The second questionnaire

2**Description**

Stool calprotectin level

Timepoint

Before the intervention and 2 months after the beginning of intervention

Method of measurement

Measured by the laboratory

3

Description

Quality of life

Timepoint

Before the intervention and 2 months after the beginning of intervention

Method of measurement

Quality of Life Questionnaire for Patients with Irritable Bowel Syndrome

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group, which consisting of 31 patients with irritable bowel syndrome and randomly selected, will receive two 250 mg capsules containing pomegranate peel extract daily for two months. These capsules are extracted from pomegranate peel by ethanolic extraction method. Questionnaires about changes in clinical symptoms and changes in their quality of life as well as fecal calprotectin levels will be assessed before the intervention and after the intervention.

Category

Treatment - Drugs

2

Description

Control group: This group, which consisting of 31 patients with irritable bowel syndrome and randomly selected, will receive two 250 mg placebo capsules daily for two months. These capsules are exactly the same shape and size as the capsules of the intervention group. Questionnaires about changes in clinical symptoms and changes in their quality of life as well as fecal calprotectin levels will be assessed before the intervention and after the intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Fatemeh Javan Ali Azar

Street address

Gastroenterology clinic, Imam Reza hospital, Golgash St, Azadi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Samie

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Web page address

<https://researchvice.tbzmed.ac.ir/>

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

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

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Javan Ali Azar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Full name of responsible person

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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