

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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)

##### Phone

+98 41 3320 1463

##### Email address

fateme.javan88@gmail.com

##### 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 size**

Target 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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**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

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614756

##### **Phone**

+98 41 3337 6923

##### **Email**

Fateme.javan88@gmail.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr Mohammad Samie

##### **Street address**

Tabriz University Of Medical Science, Attar Neyshabouri St, Pishghadam Sq, Tabriz, Iran

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614766

##### **Phone**

+98 41 3335 7310

##### **Email**

research-vice@tbzmed.ac.ir

##### **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

**Street address**

No. 6, 5th Floor, B block, Shafagh Tower, Ghanoon St, Valiasr St, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5157714119

**Phone**

+98 41 3320 1309

**Email**

Fateme.javan88@gmail.co

**Person responsible for scientific 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

**Street address**

No. 6, 5th floor, B block, Shafagh Tower, Ghanoon St, Valiasr St

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5157714119

**Phone**

+98 41 3320 1309

**Email**

Fateme.Javan88@gmail.com

**Person responsible for updating data****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

**Street address**

No. 6, 5th floor, B block, Shafagh tower, Ghanoon St, Valiasr St

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5157714119

**Phone**

+98 41 3320 1309

**Email**

Fateme.Javan88@gmail.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