

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the Effects of natural Pomegranate juice (*Punica granatum*) on CBC & inflammatory biomarkers in patients with covid-19: a Randomized clinical trial

#### Protocol summary

##### Study aim

Evaluation of the effect of natural pomegranate juice on inflammatory biomarkers and CBC in patients with Covid 19

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 48 patients with Covid 19, Randomization will be done with block random sampling

##### Settings and conduct

This study will be performed in 48 patients with Covid-19 in Shahid Jalil Hospital in Yasuj. Patients are randomly divided into intervention and placebo groups and will receive pomegranate juice or placebo daily for 14 days. At the beginning and end of the study, the desired variable will be examined.

##### Participants/Inclusion and exclusion criteria

48 patients with Covid 19 based on definitive diagnosis of PCR, admitted to Shahid Beheshti Hospital in Yasuj will be included in the study based on admission and non-admission Inclusion criteria: (1) Written informed consent form, (2) Age 18 years old or above, (3) Definitive diagnosis of Covid 19, (4) Acceptance for random assignment, (5) Willingness to participate in research study Non-inclusion criteria: (1) Pregnancy or lactation, (2) Other contraindications prescribed by the specialist, (6) Participate in any clinical trial

##### Intervention groups

The intervention group will receive daily 500 ml of natural pomegranate juice and the placebo group will receive daily 500 ml of water + authorized food coloring + 0.02% pomegranate emulsion, twice a day for 14 days.

##### Main outcome variables

Inflammatory biomarker include IL-6 , CRP, ESR and CBC

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150711023153N2**  
Registration date: **2021-02-28, 1399/12/10**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-02-28, 1399/12/10**

Update count: **0**

##### Registration date

2021-02-28, 1399/12/10

##### Registrant information

##### Name

Seyed Bahman Panahande

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3322 3505

##### Email address

panahande-b@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-28, 1399/12/10

##### Expected recruitment end date

2021-05-21, 1400/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the Effects of natural Pomegranate juice

(Punica granatum) on CBC & inflammatory biomarkers in patients with covid-19: a Randomized clinical trial

#### Public title

Evaluation of the Effects of natural Pomegranate juice (Punica granatum) in patients with covid-19

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Written informed consent form Age 18 years old or above COVID-19 diagnosis based on polymerase chain reaction (PCR) Acceptance for random assignment Willingness to participate in research study

##### Exclusion criteria:

Pregnancy or lactation IgA <61 mg/dl Disseminated intravascular coagulation or any other types of coagulopathy Severe congestive heart failure by the specialist Other contraindications prescribed by the specialist Participate in any clinical trial within the past 30 days prior to enrollment in the present study

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

#### Sample size

Target sample size: **48**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients will be randomly divided into two groups of intervention or placebo by block random sampling method based on age ( $\geq 55$  years or  $< 55$  years) and sex (male or female) in one of 8 blocks for 6 people

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Blinding of patients, health care professionals, principal investigators as well as data collectors and data analysts will be unaware of the intervention and placebo groups at the end of the study. The intervention includes a placebo or natural pomegranate juice in special bottles and exactly same in color and taste are labeled with different numbers, and the contents of these numbers will be kept in a closed envelope in the faculty and its contents will be preserved until the end of the study.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Yasuj University of Medical Sciences

##### Street address

Yasuj-Shahid Motahari Boulevard-Yasuj University of Medical Sciences

##### City

Yasuj

##### Province

Kohgiluyeh-va-Boyerahmad

##### Postal code

7591741417

#### Approval date

2021-01-20, 1399/11/01

#### Ethics committee reference number

IR.YUMS.REC.1399.181

## Health conditions studied

### 1

#### Description of health condition studied

Covid19

#### ICD-10 code

U07.1

#### ICD-10 code description

U07.1

## Primary outcomes

### 1

#### Description

Interleukin 6

#### Timepoint

Before the intervention and at the end of day 14 of the study

#### Method of measurement

Elisa Kit

### 2

#### Description

CRP

#### Timepoint

Before the intervention and at the end of day 14 study

#### Method of measurement

Elisa Kit

### 3

#### Description

Erythrocyte Sedimentation Rate (ESR)

## Timepoint

Before the intervention and at the end of day 14 of the study

## Method of measurement

Elisa Kit

## 4

### Description

CBC

### Timepoint

Before the intervention and at the end of day 14 of the study

### Method of measurement

Elisa Kit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients receiving 500 ml of natural pomegranate juice twice a day after lunch and after dinner + usual hospital medicine

#### Category

Treatment - Other

### 2

#### Description

Placebo group: Patients receiving 500 ml placebo (water + food coloring approved by the Ministry of Health + 0.02% pomegranate emulsion according to the instructions) twice a day after lunch and after dinner + usual hospital medicine

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

بیمارستان شهید جلیل یاسوج

##### Full name of responsible person

Zaker Saeedinejad

##### Street address

Yasuj, shahid gharani bulvar

##### City

yasuj

##### Province

Kohgiluyeh-va-Boyerahmad

##### Postal code

7591387493

##### Phone

+98 74 3333 7001

##### Email

saeedizaker@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Dr. Hossein Marioryad - Vice President for Research

##### Street address

Yasuj-Shahid Motahari Boulevard-Yasuj University of Medical Sciences

##### City

YASUJ

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591741417

##### Phone

+98 74 3333 7230

##### Email

panahande.b@gmail.com

##### Web page address

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

##### Full name of responsible person

mojtaba yousefi

##### Position

student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nutrition

##### Street address

Imam Hossein Square - Golestan 15 School of Health and nutrition

##### City

yasuj

**Province**  
Kohgilouyeh-va-Boyrhmad  
**Postal code**  
7591875114  
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+98 74 3322 5519  
**Email**  
mojtaba.yousefi@yums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
seyed bahman panahande  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
Imam Hossein Square - Golestan 15 School of Health and nutrition  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
seyed bahman panahande  
**Position**  
Associate professor  
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Ph.D.  
**Other areas of specialty/work**  
Nutrition  
**Street address**

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**Email**  
panahande.b@yums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is 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

### Title and more details about the data/document

All potential data can be shared after blinding

### When the data will become available and for how long

Six months after publishing

### To whom data/document is available

Researchers working in academic institutions

### Under which criteria data/document could be used

For research purposes and meta-analysis studies

### From where data/document is obtainable

Dr. Seyed bahman panahande . Faculty member of the Health and Nutrition, Yasuj University of Medical Sciences

### What processes are involved for a request to access data/document

Official letter to the researchers

### Comments