

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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 (≥ 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

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Assistant Professor
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Person responsible for updating data

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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, Yasouj University of Medical Sciences

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

Official letter to the researchers

Comments