Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 74 3322 3505

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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
Kohgilouyeh-va-Boyrahmad

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
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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
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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, Yasuj University of Medical Sciences
What processes are involved for a request to access data/document
Official letter to the researchers
Comments