Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of pomegranate tea on symptom relief of COVID-19 patients: a double-blind randomized clinical trial study

Protocol summary

Study aim
Determining and comparing the effect of pomegranate tea with placebo in relief patients' symptoms and reducing the duration of disease in patients with COVID-19

Design
66 patients with COVID-19 will be randomly assigned to two groups of placebo and intervention by a pharmacognosy specialist based on patient respiratory support and with the same ratio (1: 1). None of the researchers in the clinical phase of the study were aware of the nature of the intervention.

Settings and conduct
This study will be performed in Hajar Hospital in Shahrekord. In this double-blind study, participants, physicians, and nurses would not be aware of the nature of the medications received by each individual group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Positive SARS-CoV-2 virus test by RT-PCR method from airway samples. • Men or non-pregnant women over 18 years of age. • Significant involvement in pulmonary CT scan with a pneumonia diagnosis. • Low blood oxygen saturation or 93% in room air. • Respiratory rate above 24 per minute or more. • Patients who are taking the following medications (Amitriptyline, codeine, Desipramine, Flecainide, Fluoxetine, Ondansetron, Tramadol). Exclusion criteria: • The physician's decision to leave the study based on the patient's condition. • Allergies or hypersensitivity reactions to the drug. • Inability to swallow or drink. • Transfer the patient to more specialized medical centers. • Transferring the patient to the intensive care unit.

Intervention groups
Participants in the intervention group will receive pomegranate syrup 4 times a day, 10 cc each time, diluted in 50 to 100 cc of hot boiled water as pomegranate tea, and participants in the control group will receive the placebo in the similar condition.

Main outcome variables
Time to clinical improvement, Duration of Hospitalisation and Time to clinical deterioration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200416047104N1**
Registration date: **2020-04-23, 1399/02/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-23, 1399/02/04**
Update count: **0**

Registration date
2020-04-23, 1399/02/04

Registrant information

Name
Zahra Lorigooini

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-06-21, 1399/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of pomegranate tea on symptom relief of COVID-19 patients: a double-blind randomized clinical trial study

Public title
Effect of pomegranate tea on symptom relief of COVID-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Positive diagnostic specimen on RT-PCR Men or non-pregnant women over 18 years of age Significant involvement in pulmonary CT scan with pneumonia diagnosis Oxygen saturation (Sao2) of blood less than or equal to 93% in room air Respiratory rate above 24 per minute

Exclusion criteria:
Taking medications: (Amitriptyline, Codeine, Desipramine, Flecainide, Fluoxetine, Ondansetron, Tramadol) Pregnancy and lactation

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly assigned to study by randomized class blocking according to the respiratory support groups they received (no need for respiratory support, respiratory support with low oxygen flow, respiratory support with high oxygen flow, respiratory support with oxygen storage, non-invasive ventilation) In four-person blocks, they are assigned to groups A and B and randomly using the software. Patient allocation will be blinded and clinical researchers will not be aware of the individual intervention group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, all participants in the study, physicians and nurses responsible for collecting patients' clinical and laboratory data, were unaware of the intervention (placebo or drug) that each person received; placebo by oral and flavoring similar to the drug. Participants in the study and nurses are unaware of the presence of pomegranate extract. All medications will be coded by a pharmacognosy specialist, and randomization will be performed by the same person as described in the relevant section, and none of the colleagues in charge of tracking patients will know about even the groups of patients.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences

Street address
Shahrekord University of Medical Sciences, Kashani Blvd

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Chahar-Mahal-va-Bakhtiari

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Approval date
2020-04-12, 1399/01/24

Ethics committee reference number
IR.SKUMS.REC.1399.017

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Time to clinical improvement.

Timepoint
Every day after randomization.

Method of measurement
Patients' medical records.

2

Description

Time to clinical deterioration.
Timepoint
Every day after randomization.
Method of measurement
Patients' medical records.

3

Description
Duration of Hospitalization.
Timepoint
Every day after randomization.
Method of measurement
Patients' medical records.

Secondary outcomes

1

Description
Mortality
Timepoint
21th day after randomization.
Method of measurement
Patients' medical records.

2

Description
Clinical improvement in first 7 days of intervention.
Timepoint
7th day after randomization.
Method of measurement
Patients' medical records.

3

Description
Fever
Timepoint
Every day after randomization
Method of measurement
Thermometer

4

Description
Respiratory rate
Timepoint
Every day after randomization
Method of measurement
Clinical observation and examination

5

Description
Oxygen saturation
Timepoint
Every day after randomization
Method of measurement
Pulse Oximeter

6

Description
Systolic blood pressure
Timepoint
Every day after randomization
Method of measurement
Clinical observation and examination

7

Description
Duration of respiratory support
Timepoint
Every day after randomization
Method of measurement
Patients' medical records

8

Description
Cough
Timepoint
Every day after randomization
Method of measurement
Clinical observation and history taking

9

Description
Dyspnea
Timepoint
Every day after randomization
Method of measurement
Clinical observation and history taking

10

Description
Fatigue
Timepoint
Every day after randomization
Method of measurement
Clinical observation and history taking

11

Description
Myalgia
Timepoint
Every day after randomization
Method of measurement
Clinical observation and history taking

12

Description
Headache
Timepoint
Every day after randomization
Method of measurement
Clinical observation and history taking

13

Description
Sore throat
Timepoint
Every day after randomization
Method of measurement
Clinical observation and history taking

14

Description
Chills
Timepoint
Every day after randomization
Method of measurement
Clinical observation and history taking

15

Description
Gastrointestinal adverse events
Timepoint
Every day after randomization
Method of measurement
Clinical observation and history taking

16

Description
Thirsty
Timepoint
Every day after randomization
Method of measurement
Clinical observation and history taking

17

Description
Duration of respiratory support
Timepoint
Every day after randomization
Method of measurement
Patients' medical records

18

Description
Transmission to ICU
Timepoint
Every day after randomization
Method of measurement
Patients' medical records

19

Description
SARS-CoV-2 test result
Timepoint
21th day after randomization
Method of measurement
RT-PCR

20

Description
Blood cell count
Timepoint
Two days in between after randomization
Method of measurement
The complete blood count (CBC)

21

Description
CRP level
Timepoint
Two days in between after randomization
Method of measurement
Blood test

22

Description
Serum creatinine
Timepoint
Two days in between after randomization
Method of measurement
Blood test

23

Description
Lactate dehydrogenase
Timepoint
Two days in between after randomization
Method of measurement
Blood test

24

Description
Ferritin
Timepoint
Two days in between after randomization
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Participants in the intervention group receive 4 times a day (after each meal and before bedtime) and 10 ccs of pomegranate syrup for 21 days each time, in addition to standard treatment.
Pomegranate tea is prepared by dilution 10 ccs of pomegranate syrup in 50 to 100 cc of warm boiled water and kept in the mouth for a while before swallowing.
Category
Treatment - Drugs

2

Description

Control group: In addition to standard treatment, the control group receives a placebo in completely similar conditions. The placebo will be produced in terms of taste and color similar to the original drug and will be used in completely similar conditions.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar hospital

Full name of responsible person
Vahid Reisi-Vanani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Dr. Zahra Lorigooini

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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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
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
Yes - There is 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 mounts 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. Zahra lorigooini, Medical Plants Research Center, School of Medicine, Shahrekord University of Medical Sciences, Rahmatieh

What processes are involved for a request to access data/document
Official letter to the researchers

Comments