

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Pilot study of the Grapefruit seed extract adjuvant therapy on COVID-19

#### Protocol summary

##### Study aim

Determination of the grapefruit seed extract efficacy in the treatment of COVID-19 as an adjuvant therapy

##### Design

Two arms, double-blind, parallel-group randomized pilot trial with 15 patients in each arm that assigned by coin's head or tail.

##### Settings and conduct

A pilot intervention study on 15 volunteer patients with COVID-19 at Masih Daneshvari Hospital in Tehran confirmed by PCR. Patients' information is considered confidential and they enter the study with informed consent and can leave the study at any time if they wish to do so. The intervention is the administration of grapefruit seed extract or placebo, which is administered orally to patients 10 drops three times a day for 7 days.

##### Participants/Inclusion and exclusion criteria

All infectious ward inpatients in Masih Daneshvari hospital above 18 and under 60 years old, that their COVID-19 is confirmed by PCR test, and don't have any cardiovascular, diabetes, renal, autoimmune, and allergy disease, and do not consume any cardiovascular drugs, anticoagulants, antidiabetes, anti hypercholesteremia, immunosuppressive and anti-allergy drugs, and are designated to take daily Kaletra

##### Intervention groups

Ten drops of grapefruit seed extract or placebo as adjuvant therapy are added to the COVID-19 pharmacotherapy regimen and its efficacy and adverse effects will be evaluated.

##### Main outcome variables

The findings of the study are oxygen saturation, disease symptoms, and medication side effects that are checked daily and the patient's paraclinic involves biochemical tests, lymphocyte count, ESR, CRP, which are tested at 7-day intervals.

#### General information

##### Reason for update

The person responsible for updating the information has been changed

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140312016968N2**

Registration date: **2020-11-01, 1399/08/11**

Registration timing: **retrospective**

Last update: **2020-12-07, 1399/09/17**

Update count: **1**

##### Registration date

2020-11-01, 1399/08/11

##### Registrant information

##### Name

Seyed Ali Ziai

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 9969

##### Email address

aliziai@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-21, 1399/02/02

##### 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

Pilot study of the Grapefruit seed extract adjuvant

therapy on COVID-19

## Public title

Study of the effects of grapefruit extract on COVID-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Ages between 18-60 years Inpatients of the wards Daily Lopinavir / Ritonavir PCR confirmed COVID-19 Without background disease

### Exclusion criteria:

Age above 60 and below 18 Cardiovascular disease Diabetes Autoimmune disease Renal disease Respiratory distress on admission time Allergy history Consumption of cardiovascular drugs, anti diabetes, anti coagulants, anti HIV, anti cholesterol, immunosuppressive, and cancer chemotherapy agents Reluctance to participate in the study

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

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

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients with inclusion criteria are allocated to a medication or placebo category based on coin chance

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Only the principal investigator knows the codes and all of the clinical staff are blinded. Containers containing the medicine/ placebo, their color and viscosity are the same, but their taste is different.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of

Medical Sciences

## Street address

Shahid Beheshti University of Medical Science, Arabi St., Daneshjoo Blvd., Velenjak

## City

Tehran

## Province

Tehran

## Postal code

1985717443

## Approval date

2020-04-06, 1399/01/18

## Ethics committee reference number

IR.SBMU.RETECH.REC.1399.041

## 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

O2 saturation

#### Timepoint

Measurement of oxygen saturation every day during the study

#### Method of measurement

Pulse oximetry device

### 2

#### Description

Adverse drug reaction

#### Timepoint

Daily recording of possible adverse effects of the extract

#### Method of measurement

Observational recording

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For 7 days, three times a day, each time 10 drops of grapefruit seed extract in addition to routine medication that is Kaltra receive. The medicine should be poured in half a glass of water and consumed. The drug uses the GSE brand made by Nutribiotic Company, which is dissolved in oral glycerin, which has

been poured and labeled to be hidden in plastic dropper containers.

**Category**

Treatment - Drugs

**2****Description**

Control group: For 7 days, three times a day, each time 10 drops of orange concentrate in addition to routine medication that is Kaltra receive. The medicine should be poured in half a glass of water and consumed. The placebo solution is Sunich orange extract, which is poured into the same plastic dropper containers and labeled the same as the medicine, only the code is different.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Masih Daneshvary hospital

**Full name of responsible person**

Dr. Aliakbar Velayati

**Street address**

Darabad, Shahid Bahonar St.,

**City**

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**Province**

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1956944413

**Phone**

+98 21 2610 5050

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saziai@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Afshin Zarghi

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Shahid Arabi St., Daneshjoo Blvd., Velenjak

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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**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Majid Marjani

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Infectious diseases

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Ali Ziai

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmacology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Ramin Pouriran  
**Position**  
Medical student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Medicine  
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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

Yes - There is a plan to make this available

### Informed Consent Form

No - There is not 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

Yes - There is a plan to make this available

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

Generalities are presented as a printed article. And detailed information is available to the researcher and is provided whenever requested.

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

Since the publication of the article

### To whom data/document is available

Researchers and regulatory organizations

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

To review the results by regulatory agencies and researchers

### From where data/document is obtainable

To the principal investigator and clinical associate

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

By email to the principal investigator aliziai@sbmu.ac.ir

### Comments