Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 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, immunsuppressive, 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
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2610 5050

Email
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

Street address
Shahid Arabi St., Daneshjoo Blvd., Velenjak

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2243 9781

Email
saziai@gmail.com

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

Street address
Darabad, Shahid Bahonar St.

City
Tehran

Province
Tehran

Postal code
1956944413

Phone
+98 21 2610 5050

Email
marjani216@hotmail.com

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

Street address
Koodakyar St., daneshjoo Blvd., Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9969

Email

saziai@gmail.com

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

Street address

Koodakyar St., Daneshjoo Blvd., Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9969

Email

ramin.pourk@gmail.com

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