

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of Viola odorata syrup on alleviating the manifestations of COVID-19 (Corona) infection: A double-blind placebo controlled trial

Protocol summary

Study aim

Evaluation of the effects of violet syrup on the recovery of outpatient coronary patients

Design

A double-blind, with placebo, randomized clinical trial with 4 blocks, phase 3, 100 patients, Stata software was used for randomization.

Settings and conduct

Patients referred to Al-Zahra Hospital (Isfahan Corona Center) for whom the diagnosis of COVID-19 was confirmed based on clinical symptoms and blood oxygen saturation percentage along with lung CT scan with the approval of a Radiologist and / or positive PCR, did not require hospitalization, outpatient medical and protective treatment. Patients and physician are unaware of the group allocation.

Participants/Inclusion and exclusion criteria

Patients based on clinical signs and the percentage of oxygen saturation in the blood with CT scan of the lung with the approval of a radiologist and / or PCR confirmed for them and do not need to be hospitalized, to be treated on an outpatient basis for medical and conservative treatment Saturated oxygen pressure greater than or equal to 90% Age range of patients 15 to 75 years in both sexes Diabetic patients, has diarrhea, people with a history of allergies to herbal products and medicines are not included in the study

Intervention groups

Intervention group receive study drug in addition to usual drugs. Control group receive placebo with the usual drugs

Main outcome variables

Improving the patient's clinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190409043215N2**

Registration date: **2021-02-14, 1399/11/26**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-14, 1399/11/26**

Update count: **0**

Registration date

2021-02-14, 1399/11/26

Registrant information

Name

Ali akbar Safari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3464 3176

Email address

safaria@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-20, 1399/09/30

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Viola odorata syrup on alleviating the manifestations of COVID-19 (Corona) infection: A double-blind placebo controlled trial

Public title

Effect of Viola odorata syrup on alleviating the manifestations of COVID-19 (Corona) infection: A double-blind placebo controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referred to Al-Zahra Hospital (Isfahan) who diagnosed COVID-19 based on clinical symptoms and blood oxygen saturation along with CT scan of the lung with the approval of a radiologist and / or positive PCR for them. Blood oxygen saturation greater than or equal to 90%. The age range of patients is 15 to 75 years Both sexes Satisfaction to participate in the study

Exclusion criteria:

Diabetic patients Patients with allergies to herbal products Severe forms of covid-19 disease (respiratory rate > 24 or percent of blood saturated oxygenation < 90%) Patients with diarrhea

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced block randomization technique with 4 blocks. Using Stata software random number chains from 1 to 6 to reach the desired sample size was produced. Prepared random assignment sequences for individuals was placed in sealed envelopes (Sealed) and numbered with a 5-digit serial number, by a third party who did not play a role in the design of the study. All envelopes (100 envelopes) have a random dedicated serial number that was immediately opened after completing basic information and basic tests to allocate individuals to groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs were coded so participant, clinician and therapist were unaware of their content.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Medicine, Tehran University of Medical Sciences

Street address

Medical School, Poursina St, Ghods St, Enghelab St, Tehran

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2020-11-22, 1399/09/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.784

2

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences, School of Medicine

Street address

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, School of Medicine

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-02-03, 1399/11/15

Ethics committee reference number

IR.MUI.MED.REC.1399.1022

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Severity of shortness of breath

Timepoint

Once a day for 6 days

Method of measurement

Questionary

2

Description

Intensity of cough

Timepoint

Once a day for 6 days

Method of measurement

Questionnaire

3

Description

Blood oxygen

Timepoint

Once a day for 6 days

Method of measurement

Pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: recipient of violet syrup, in the amount of 10 ml three times a day for 5 days. Violet syrup contains aqueous extract of violet flowers and leaves and sugar, which has a manufacturing license from the Food and Drug Administration, number 6599807159453166.

Category

Treatment - Drugs

2

Description

Control group: receiving placebo syrup, in the amount of 10 ml three times a day for 5 days. Placebo syrup contains water, sugar and a little food coloring to look like medicine.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital (Isfahan)

Full name of responsible person

Mohammad Sadegh Adel Mehraban

Street address

Al-Zahra Educational and Medical Center, Soffeh Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Fax

+98 31 3669 1510

Email

sadeghadel@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Central University Organization, sixth floor, Vice Chancellor for Research and Technology corner, Corner of Ghods Street, Keshavarz Boulevard, Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Email

vcr@tums.ac.ir

Grant name

Covid 19 Research Grant

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Barij Essence Pharmaceutical Company

Full name of responsible person

Leila Mohammad Taghizadeh

Street address

No. 78, Marzadaran St., between Ariaifar and Sarsabz

City

Tehran

Province

Tehran

Postal code

1464653465

Phone

+98 21 4421 2044

Fax

+98 86 4446 5187

Email

kashanileila138@yahoo.com

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Barij Essence Pharmaceutical Company

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Industry

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

Tehran University of Medical Sciences

Full name of responsible person

Meysam Shirzad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No. 27, Sarparast St, Taleghani St

City

Tehran

Province

Tehran

Postal code

1464653465

Phone

+98 21 8897 4535

Fax**Email**

shirzadmd@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Meysam Shirzad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

No. 27, Sarparast St, Taleghani St.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8897 4535

Email

shirzadmd@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Ali Akbar Safari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

45 meters Golshahr Street, Shahid Saffarian Street

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3774

Email

safariali1350@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Clinical study report

When the data will become available and for how long
After completing the study

To whom data/document is available
working at the University

Under which criteria data/document could be used
For research purposes

From where data/document is obtainable
Ali akbar safari

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

Comments