Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Public title

Effect of Viola odorata syrup on aleviating 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 percnt 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

Isfehan

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
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Isfehan
Postal code
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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 Technologycorner, Corner of Ghods Street, Keshavarz Boulevard, Tehran
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Province
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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 Scinces
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, Marzdaran St., between Ariafar and Sarsabz

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Tehran
Province
Tehran
Postal code
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Fax
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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
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Person responsible for scientific inquiries

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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
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Province
Alborz
Postal code
3198764653
Phone
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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