

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Study of the effectiveness of "SALIRAVIRA" as a natural product containing Licorice, Cone flower, Ginseng, Hyssop, Rhubarb and Rosemary extracts on the recovery of COVID-19 patients

Protocol summary

Study aim

Determining the effectiveness of "SALIRAVIRA" as a natural product containing of Licorice, Coneflower, Ginseng, Hyssop, Rhubarb and Rosemary extracts to coronavirus load in COVID-19 patients

Design

Randomized blind controlled trial with two parallel groups

Settings and conduct

Patients are recruited in the infectious diseases department of Imam Khomeini Hospital complex and a clinic; assigned in two parallel groups randomly. Participants and outcome evaluators are blind to the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: COVID-19 patient confirmed by positive PCR-viral load test, Having some or all of the symptoms include fever, fatigue, muscle aches (body aches), headache, cough, chest tightness, and shortness of breath. Exclusion criteria: Malignant tumors and other acute systemic diseases and respiratory problems Life-threatening comorbidity, Use of any other herbal substance. Pregnancy, Lactation and drug and Alcohol addiction.

Intervention groups

Intervention group: Patients who receive "SALIRAVIRA" along with standard treatments as add on therapy.
Control group: Patients who receive only standard treatments.

Main outcome variables

Viral clearance, Improving the symptoms of the disease such as fever and shortness of breath

General information

Reason for update

Addition a site for patient recruitment (Hospital)

Acronym

IRCT registration information

IRCT registration number: **IRCT20201220049771N1**
Registration date: **2020-12-31, 1399/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-13, 1400/03/23**

Update count: **2**

Registration date

2020-12-31, 1399/10/11

Registrant information

Name

Tahereh Hosseinabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0118

Email address

hosseinabadi.t@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effectiveness of "SALIRAVIRA" as a natural

product containing Licorice, Cone flower, Ginseng, Hyssop, Rhubarb and Rosemary extracts on the recovery of COVID-19 patients

Public title

study of the effectiveness of "SALIRAVIRA" as a natural product on the treatment of COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical confirmation of coronavirus infection COVID-19 positive test reporting by RT-PCR Cases with contact history with a COVID-19 patients in last 10 days Lung involvement below 20% - Using CT-Scan

Exclusion criteria:

Pregnancy and Lactation cases Cases with malignant tumors and other acute systemic diseases or special indication Patients suffering from autoimmune diseases like Psoriasis, ALS and MS Patients with comorbidity of respiratory life-threatening problems Addiction to drugs and alcohol Participation to another clinical trial for COVID-19

Age

From **12 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be assigned to two groups by block randomization method. In order to minimize the probability of sequence prediction, blocks with variable (4 and 6) size will be used. The randomization ratio will be 1:1. Randomization will be done using Random allocation software. Allocation concealment will be done by assigning unique codes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Pharmacy and Nursing & Midwifery - Shahid Beheshti University of Medic

Street address

NO 2660, Vali-asr Ave, Tehran

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Tehran

Province

Tehran

Postal code

1996835113

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.276

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

Viral Clearance

Timepoint

At the beginning of the study and and 4, 8 days after intake

Method of measurement

Polymerase chain reaction (PCR)

2

Description

Fever and symptoms

Timepoint

At the beginning of the study and daily during treatment after intake

Method of measurement

Using a thermometer and clinical diagnosis

3

Description

shortness of breath

Timepoint

At the beginning of the study and daily during treatment after intake

Method of measurement

Medical diagnosis

Secondary outcomes

1

Description

olfactory (sense of smell)

Timepoint

At the beginning of the study and daily during treatment after intake

Method of measurement

Questionnaire with interview

2

Description

sense of taste

Timepoint

At the beginning of the study and daily during treatment after intake

Method of measurement

Questionnaire with interview

Intervention groups

1

Description

Intervention group: Patients who receiving "SALIRAVIRA" containing mentioned extracts orally and respiratory spray at the same time in addition to standard treatments of COVID-19: 1- Oral; SALIRAVIRA tablet 750 mg; containing 500 mg of plant extracts mentioned before; 4 times daily, Once every 6 hours (tablets are packed in blisters contain 10 tablet and will be provided to each case for the duration of treatment, ie 32 tablet) All process of extraction, production and packaging done under GMP conditions in Mimdaroo pharmaceutical company. 2 - SALIRAVIRA respiratory spray (20ml), which contains plant extracts mentioned before will be used 4 times daily, once every 6 hours, spay will be used nasal or throat along with tablets. SALIRAVIRA spray contains 100mcl of plant extract per puff and its daily dose is 400 mcl based on references. All stages of production and packaging of SALIRAVIRA spray have been done under GMP conditions and in Mimdaroo Pharmaceutical company. The duration of treatment will be 8 days.

Category

Treatment - Drugs

2

Description

Control group: Patients receiving standard treatments for COVID-19 disease for 8 days. Standard treatment is determined according to the protocols and guidelines of the Ministry of Health and is performed in all centers.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Infectious Disease., Imam Khomeini Hospital Complex

Full name of responsible person

Hamid Emadi

Street address

Gharib St., Keshavarz Blvd. Imam Khomeini Hospital

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2

Recruitment center

Name of recruitment center

Infectious Disease Dept., Tehran Heart Center

Full name of responsible person

Naser Mohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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http://pharmacy.sbmu.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
MimDaroo Pharmaceutical Company
Proportion provided by this source
100
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

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Person responsible for general inquiries

Contact

Name of organization / entity
MimDaroo Pharmaceutical Co.
Full name of responsible person
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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data can be shared after de-identification

When the data will become available and for how long

Data will be available from April, 2030

To whom data/document is available

Academics employed at various research/university institutions and the industry.

Under which criteria data/document could be used

Using the de-identified data will be allow for scientific research by academics, including faculty members and

students. In this case, by sending the request and reviewing it, the requested data will be provided.

From where data/document is obtainable

At first should refer to a person responsible for general inquiries of the clinical trial and then to the principal investigator.

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

1- The applicant would be asked to provide a written formal request letter, containing the importance of the data . 2- Following the receipt of request letter, the data would be provided in no more than one week.

Comments