

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 May 2021

### 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: **2021-02-21, 1399/12/03**

Update count: **1**

##### 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

#### City

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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1419733141

#### **Phone**

+98 21 6658 1598

#### **Email**

emadiham@tums.ac.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Infectious Disease Dept., Tehran Heart Center

##### **Full name of responsible person**

Naser Mohammadi

##### **Street address**

North Kargar Ave., Corner of Jalal Al Ahmad Highway

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1411713138

##### **Phone**

+98 21 8802 9600

##### **Email**

nasmoh@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Tahereh Hosseinabadi

##### **Street address**

No.2660, Vali-e-asr Ave.,Tehran,Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1996835113

##### **Phone**

+98 21 8820 0118

##### **Fax**

+98 21 8866 5250

##### **Email**

hosseinabadi.t@gmail.com

##### **Web page address**

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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
MimDaroo Pharmaceutical Co.  
**Full name of responsible person**  
Saleh Ramezani Khorshiddoust  
**Position**  
Member of Board  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
No. 04, 4th alley, Ghanbarzadeh St. Shahid Beheshti St., Tehran, Iran  
**City**  
tehran  
**Province**  
Tehran  
**Postal code**  
1533853613  
**Phone**  
+98 21 9662 1410  
**Email**  
Saleh.rkh@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Tahereh Hosseinabadi  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
No.2660, Vali-asr Ave.

**City**  
tehran  
**Province**  
Tehran  
**Postal code**  
1996835113  
**Phone**  
+98 21 8820 0118  
**Fax**  
+98 21 8866 5250  
**Email**  
hosseinabadi.t@gmail.com  
**Web page address**  
<http://pharmacy.sbmu.ac.ir/index.jsp?pageid=32628&p=1>

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mimdaroo Pharmaceutical Co.  
**Full name of responsible person**  
Fatemeh Azadinia  
**Position**  
Consultant  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Others  
**Street address**  
No. 4, 4th alley, Ghanbarzadeh St. Shahid Beheshti St., Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1533853613  
**Phone**  
+98 21 9662 1410  
**Fax**  
+98 21 9662 1410  
**Email**  
Saleh.rkh@gmail.com  
**Web page address**  
<https://www.mimdaroo.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

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**