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)

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+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
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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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North Kargar Ave., Corner of Jalal Al Ahmad Highway
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1411713138
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nasmoh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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No.2660, Vali-e-asr Ave.,Tehran,Iran
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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
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No. 04, 4th alley, Ghanbarzadeh St. Shahid Beheshti St., Tehran, Iran
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Person responsible for scientific inquiries

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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
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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