Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of herbal food product (Shad syrup) in patients with COVID 19

Protocol summary

Study aim
Evaluation of the effect of herbal food product (Shad syrup) in patients with COVID19
Design
Clinical trial with control group, with parallel groups , non-blind, randomized using random numbers table, Phase three on 100 patients
Settings and conduct
Taleghani hospital, Tehran,Iran
Participants/Inclusion and exclusion criteria
inclusion criteria: confirmed COVID-19 infection with Lab tests not considering sign and symptoms suspected COVID-19; infection based on national protocol include the patients who has respiratory signs and pulmonary unilateral or bilateral multilobar infiltration in CT scan or chest radiography; suspected patient to pneumonia with uncommon rapid deterioration and fast worsening of clinical status and not responding to proper treatments; age 30 to 65. Exclusion criteria: Late visit more than 5 days of onset of symptoms; pregnancy and breastfeeding; allergy history; complicated bacterial infection severe and critical patients (ARDS and MODS); patient in recovery phase
Intervention groups
Intervention group: persacivir. Control group: placebo
Main outcome variables
death; fever (temperature); SPO2; CRP; ESR; LDH; SGPT; SGOT; BUN; Cr

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150815023620N9**
Registration date: **2021-03-13, 1399/12/23**
Registration timing: **retrospective**
Last update: **2021-03-13, 1399/12/23**
Update count: **0**
Registration date
2021-03-13, 1399/12/23

Registrant information
Name
Mohammadreza Moshari
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-04-01, 1399/01/13
Expected recruitment end date
2020-08-01, 1399/05/11
Actual recruitment start date
2020-04-01, 1399/01/13
Actual recruitment end date
2020-08-01, 1399/05/11
Trial completion date
2020-08-01, 1399/05/11

Scientific title
Evaluation of the effect of herbal food product (Shad syrup) in patients with COVID 19

Public title
Evaluation of the effect of herbal food product in patients with COVID 19
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
confirmed COVID-19 infection with Lab tests not considering sign and symptoms suspected COVID-19 infection based on national protocol include the patients who has respiratory signs and pulmonary unilateral or bilateral multilobar infiltration in CT scan or chest radiography suspected patient to pneumonia with uncommon rapid deterioration and fast worsening of clinical status and not responding to proper treatments age 30 to 65
Exclusion criteria:
late visit more than 5 days of onset of symptoms pregnancy and breastfeeding alergy history complicated bacterial infection severe and critical patients (ARDS and MODS) patient in recovery phase

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **150**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
With simple randomization and using a random number table and individual randomization unit. To randomize, we use a table consisting of random digits 0 to 9. Each digit of this table is repeated the same on average. There is no pattern of recognizable numbers. In this method, each number is assigned to a treatment group. We start from the first line of the table and move down line by line. For the two treatments, we put the numbers 0 to 4 for treatment A and the numbers 5 to 9 for treatment B. The numbers in the first line of the table are as follows: 0,5,2,7,8,4,3,7,4,1,6,8,3,8,5,1,5,6,9,6, ... Now for people based on the above numbers, we have the following allocation: A, B, A, B, B,... We will continue the above process until the two groups are completed.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences
Street address
Anesthesiology Research Center,Taleghani Hospital Tehran, Iran
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Province
Tehran
Postal code
1985711151

Approval date
2020-05-30, 1399/03/10

Ethics committee reference number
IR.SBMU.RETECH.REC.1399.142

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
Death

Timepoint
daily

Method of measurement
Patient record

2

Description
Fever (temperature)

Timepoint
Daily

Method of measurement
Thermometer

3

Description
SPO2

Timepoint
Daily

Method of measurement
Pulse oximetry

4

Description
CRP

Timepoint
Daily

Method of measurement
Biochemical testing

5

Description
ESR
Timepoint
Daily
Method of measurement
ESR Reader

6

Description
LDH
Timepoint
Daily
Method of measurement
Biochemical testing

7

Description
SGPT
Timepoint
Daily
Method of measurement
Biochemical testing

8

Description
SGOT
Timepoint
Daily
Method of measurement
Biochemical testing

9

Description
BUN
Timepoint
Daily
Method of measurement
Biochemical testing

10

Description
Cr
Timepoint
Daily
Method of measurement
Biochemical testing

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Shad syrup. The dosage of the syrup is 5 cc with 10 cc of water every 4 hours for the first two days and 5 cc every 6 hours for the next two days, which is given to the patient by the ward nurse and its consumption is monitored.
Category
Treatment - Drugs

2

Description
Control group: placebo. The dose is equivalent to non-drug syrup for the first two days every 4 hours 5 cc with 10 cc of water and the next two days every 6 hours 5 cc which is given to the patient by the ward nurse and its consumption is monitored.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Taleghani hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Sbmu Univercity

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Mohammadreza Moshari
Position
Assisstant professor
Latest degree
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Other areas of specialty/work
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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

some of information of main outcome will share

When the data will become available and for how long

from 2021

To whom data/document is available

researchers in universities

Under which criteria data/document could be used

use of all shared data is allowed with permission

From where data/document is obtainable

dr reza moshari rmoshari@sbmu.ac.ir

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

send an emal and take a permission

Comments