

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2243 2595

###### Email address

rmoshari@sbmu.ac.ir

##### 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 allergy 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

**City**

Tehran

**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**

Reza Moshari

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Taleghani hospital , shahid arabi street, Tehran, Iran

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<http://taleghani.sbmu.ac.ir/index.jsp?pageid=3531&p=1>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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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**  
Assistant professor  
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Specialist  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Other areas of specialty/work**  
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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 email and take a permission

**Comments**