

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Evaluation effectiveness of Shallomin syrup compared with current treatment protocol on the elimination of clinical symptoms and duration of hospitalization in admitted patients with COVID-19: A double-blind, parallel-group, multicenter, and randomized controlled trial

Protocol summary

Study aim

Treatment of of COVID-19 patients by shallomin syrup

Design

This parallel-group, double-blind, and the randomized controlled trial is randomized by designing a table using blocks of size 6. The randomization unit was the individual, the randomization sequence was created using WinPEPI program (version 11.43) and was stratified with a 1:1 allocation using a random block of size 6, and allocation concealment was done by assigning unicodes. This study has been designed on 90 patients.

Settings and conduct

This study will be carried out in three Infection Departments of Razi, Taleghani, and Sina hospitals in Ahvaz. The study is designed as a double-blinded study. The method of blinding is allocation concealment using a specific number for each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: COVID-19 patients who show specified COVID-19 clinical symptoms; positive RT-qPCR test result; provided informed consent. Exclusion criteria: Pregnant and lactating women; patients with a history of dangerous underlying diseases; individuals who exhibit specific allergic reactions to shallomin syrup.

Intervention groups

The intervention group: patients will receive their current protocol drugs plus Shallomin syrup for six days. The control group: patients will receive their current protocol drugs plus placebo syrup for six days.

Main outcome variables

Hospitalization duration; Death in hospital; Blood oxygen saturation; Fever

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200504047295N1**

Registration date: **2020-09-16, 1399/06/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-16, 1399/06/26**

Update count: **0**

Registration date

2020-09-16, 1399/06/26

Registrant information

Name

Mansour Amin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8204

Email address

mnsamin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-10, 1399/05/20

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation effectiveness of Shallomin syrup compared with current treatment protocol on the elimination of clinical symptoms and duration of hospitalization in admitted patients with COVID-19: A double-blind, parallel-group, multicenter, and randomized controlled trial

Public title

Effectiveness of Shallomin syrup on patients affected by COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

COVID-19 patients who have clinical signs of COVID-19 infection such as fever, cough, sputum production, sore throat. Patients with the positive CT scan Patients with the positive RT-qPCR for corona virus 2019 Patients who declare informed consent for enrollment in this study.

Exclusion criteria:

Pregnant women (based on WHO protocol) Lactating women (based on WHO protocol) Individuals who exhibit specific allergic reactions to shallomin syrup. Patients with heart failure, kidney failure, hepatitis, hemophilia, thalassemia or leukemia

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

This parallel-group, double-blind, and the randomized controlled trial is randomized by designing a table using blocks of size 6. The randomization unit was the individual, the randomization sequence was created using WinPEPI program (version 11.43) and was stratified with a 1:1 allocation using a random block of size 6, and allocation concealment was done by assigning unicodes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blinded: The way of blinding this is that the main investigator and the participants are unaware of the prescription drug. The drugs of both groups are in the containers of a dark color and in the same odor and color. The syrups are distinguished only by mentioning the number, and the list of numbers are given to the statistical consultant for subsequent data analysis.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan boulevard

City

Ahvaz

Province

Khouzestan

Postal code

6135715753

Approval date

2020-03-04, 1398/12/14

Ethics committee reference number

IR.AJUMS.REC.1398.995

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes**1****Description**

Hospitalization duration

Timepoint

About one week after starting the treatment

Method of measurement

Clinical and laboratory questionnaire

2**Description**

Death in hospital

Timepoint

About one week after starting the treatment

Method of measurement

vital signs

3

Description

Blood oxygen saturation

Timepoint

Every day

Method of measurement

Pulse blood oximeter

4

Description

Fever

Timepoint

Every day

Method of measurement

Oral thermometer

Secondary outcomes

1

Description

Complete Blood Count (CBC)

Timepoint

The first and end of intervention week

Method of measurement

H one devise

2

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

The first and end of intervention week

Method of measurement

Sediment pipette

Intervention groups

1

Description

Intervention group: COVID-19 patients will receive 10 ml of shalomin syrup every 6 hours for six days.

Category

Treatment - Drugs

2

Description

Control group: COVID-19 patients will be treated with placebo syrup, 10 ccs per 6 hours for six days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Afshin Talebi

Street address

No. 61965 14941, Palestine Ave., in front of the governorship institution

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Ahvaz

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2

Recruitment center**Name of recruitment center**

Taleghani Hospital

Full name of responsible person

Mohammad Jafar Yadyad

Street address

Amananiye Ave., Mostaan St., Ahvaz., Khozestan province, Iran

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yadyad-m@ajums.ac.ir

3

Recruitment center**Name of recruitment center**

Sina Hospital

Full name of responsible person

Mohammad Jafar Yadyad

Street address

Kot Abdullah, Imam Ali square, at the end of Ayatollah Behbahani highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Microbiology Department, School of Medicine, Ahvaz Jundishapur University of Medical Sciences, Golestan avenue, Olom Pezeshki boulevard

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badavim@yahoo.com

Grant name

Faculty Research Grants (FRGs)

Grant code / Reference number

IR.AJUMS.REC.1398.995

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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**

Ahvaz University of Medical Sciences

Full name of responsible person

Mansour Amin

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Duration of hospitalization, death, clinical symptoms, age and sex of COVID-19 patients.

When the data will become available and for how long

during the next 4 months

To whom data/document is available

All of the people

Under which criteria data/document could be used

For treatment of the patients

From where data/document is obtainable

Through emailing to corresponding author

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

Supplementary data will be available only for qualified enthusiastic researchers

Comments