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: COVIDE-19 patients who show specified COVIDE-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
City
Ahvaz
Province
Khouzestan
Postal code
6133633366
Phone
+98 61 3373 8204
Email
afshintalebi24@gmail.com

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
City
Ahvaz
Province
Khouzestan
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6187954386
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+98 61 3373 8204
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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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61991 17111
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yadyad-m@ajums.ac.ir

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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Province
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Email
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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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Latest degree
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Other areas of specialty/work
Microbiology

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Person responsible for updating data

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

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Province
Khouzestan

Postal code
61357-15753

Phone

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Email
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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