Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Investigating the effect of oral and spray shalomine on the treatment and improvement of symptoms in patients with COVID19

Protocol summary

Study aim
Determining the effect of oral shalomine and its respiratory spray(shallot extract)on the treatment and improvement of symptoms in patients with COVID19

Design
A clinical trial with a control group,with parallel groups,double-blind,randomized,phase2,will be performed on146 patients.Sampling was block randomized.

Settings and conduct
The participants of this study are patients with COVID19 admitted to Ganjavian Hospital in Dezful in1399.A clinical trial with a control group,with parallel groups,double-blind, randomized,phase 2,will be performed on 146 patients. Sampling was block randomized.Patients are divided into two groups of 73 intervention and 73 control group.The basis of block random division based on a four-chain of combination A(intervention group)and B(control group).This study is performed in a double-blind manner.In the control group,syrups and sprays containing distilled water are used to blind patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Positiveness of corona virus test;consent to participate in the study;not receiving any drug other than the common treatment protocol of COVID19;Need for hospitalization based on blood oxygen saturation and respiratory problems Exclusion criteria:Infection with other microbial or viral infections;severe form of COVID19 disease;inability to use syrup and respiratory spray Shalomin

Intervention groups
The control group of the treatment protocol and the intervention group,in addition to receiving the main treatment protocol,use 10ml of Shalomin oral syrup every 6hours and 1puff of shalomin spray every 6hours in each nostril and 2 puffs in the throat.

Main outcome variables
Clinical status of patients;vital signs and blood oxygen saturation,blood tests;lung CTscan and(Polymerase Chain Reaction)test before Treatment is recorded and measured at intervals of 3 days after treatment with shalomine.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200725048199N1**
Registration date: **2020-08-11, 1399/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-11, 1399/05/21**
Update count: **0**

Registration date
2020-08-11, 1399/05/21

Registrant information

Name
mahnaz nosratabadi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 61 4255 2292

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-10, 1399/05/20

Expected recruitment end date
2020-09-10, 1399/06/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of oral and spray shalomine on the treatment and improvement of symptoms in patients with COVID19

Public title

Evaluation of the effect of Shalomin on the treatment and improvement of symptoms in patients with Covid 19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive coronavirus test willingness to participate in the study not receiving any medication other than the common COVID19 treatment protocol people who need to be hospitalized based on blood oxygen saturation and respiratory status.

Exclusion criteria:

Infection with other microbial or viral infections severe form of COVID19 disease inability to use syrup and respiratory spray Shalomin

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, random sampling is simple and uses a random number table. Samples are selected over a two-week period. In the next step, using block randomization, patients are divided into two groups of 73 intervention patients (oral shalomin and its respiratory spray) and a 73-member control group (without additional intervention). The basis of block random division is based on a quadruple chain of combinations A (intervention group) and B (control group).

Blinding (investigator's opinion)

Double blinded

Blinding description

In terms of blinding, this study is performed as a double-blind. In the control group, syrups and sprays containing distilled water are used to blind patients. Based on the labeling of the main drug and placebo, the researcher will also be unaware of the use of intervention in groups. Proper blinding is done in two directions (Double Blinding).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Dezful University of Medical Sciences

Street address

No. 162, Ghoncheh St., Rusta Blvd.

City

Dezful

Province

Khouzestan

Postal code

6461855869

Approval date

2020-07-07, 1399/04/17

Ethics committee reference number

IR.DUMS.REC.1399.014

Health conditions studied

1

Description of health condition studied

Coronavirus disease (COVID-19)

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Alteration of clinical and paraclinical symptoms of Covid 19 in patients

Timepoint

Once every three days after starting treatment until finally one month after starting treatment.

Method of measurement

Based on vital signs and paraclinical information.

2

Description

Corona virus test result

Timepoint

Two weeks after starting treatment

Method of measurement

Based on the results of corona virus polymerase chain reaction test

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group, in addition to receiving the approved treatment protocol for COVID19, uses Shalomin oral syrup (prepared from shallot extract) 10 cc every 6 hours and Shalomin spray 1 puff every 6 hours in each nostril and 2 puffs in the throat. To prepare the antiviral fraction, which is one of the flavonoids in the active plant ingredients, first aqueous extract is prepared from shallot plant, then column chromatography is used to separate the active ingredient from the extract and the active ingredient is separated and purified. It is then used as a syrup and spray for formulation. The formulation of the drug is a syrup containing 0.1% shalomine and 10% glycerin in double distilled water and a spray containing 0.1% shalomine and 10% ethanol in double distilled water, which will be prepared in Sadra Noor Biotechnology Pharmaceutical Company. (This drug has been patented by Dr. Mansour Amin for the treatment of herpes simplex virus type 1).

Category

Treatment - Drugs

2

Description

Control group: The control group will receive the approved treatment protocol for COVID19 without additional intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dezful University of Medical Sciences affiliated hospitals

Full name of responsible person
Mahnaz Nosratabadi

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Bud Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Dezfoul University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Dezfoul 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
Dezfoul University of Medical Sciences

Full name of responsible person
mahnaz nosratabadi

Position
Faculty of Nursing and Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
After the study, the demographic information and clinical and paraclinical status of patients and the result of their treatment will be provided to researchers in an anonymous and completely confidential manner.
When the data will become available and for how long
6 months after the publication of research results.
To whom data/document is available
Academic researchers and scientific centers
Under which criteria data/document could be used
For therapeutic and research use
From where data/document is obtainable
The first author or responsible author of the research article mahnaz.nosratabadi@gmail.com
What processes are involved for a request to access data/document
After communicating via email with the author or the first person of the published article, the accuracy and scientific status of the applicant will be checked and identified, and after confirmation, the information will be provided to the applicants as soon as possible.
Comments
Any contribution to the dissemination of science in the field of current research can be provided, we are ready to cooperate.