Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of Nutrition Bio-Safety (NBS) powder on immune system function and clinical manifestations in patients with COVID-19

Protocol summary

Study aim
Determine the effect of NBS powder on immune system function and clinical manifestations in patients with COVID-19

Design
The randomized clinical trial, parallel groups, 23 patients will be enrolled in each arms of the study.

Settings and conduct
This study will be performed in Sina hospital, Hamadan, Iran. In this study 46 patients selected based on inclusion and exclusion criteria will be divided into two groups (23 in each group) by simple randomization. Patients in control group will be prescribed standard regimen for COVID-19. Patients in intervention group in addition to the standard antiviral treatment of the two-drug regimen, NBS powder will be taken at a dose of 2 g / day for 4 weeks.

Participants/Inclusion and exclusion criteria
The confirmed COVID-19 patients through PCR over the age of 20 year and is not allergic to the powder used.

Intervention groups
In the intervention group, in addition to the standard antiviral treatment of the two-drug regimen, NBS powder will be taken at a dose of 2 g / day for 4 weeks. The control group will only receive standard antiviral treatment with a two-drug regimen.

Main outcome variables
Improve clinical signs and strengthen the immune system

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200426047206N1**
Registration date: **2020-04-28, 1399/02/09**
Registration timing: **prospective**
Last update: **2020-04-28, 1399/02/09**
Update count: **0**

Registration date
2020-04-28, 1399/02/09

Registrant information

Name
Salman Khazaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-09, 1399/02/20

Expected recruitment end date
2020-07-10, 1399/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Nutrition Bio-Safety (NBS) powder on immune system function and clinical manifestations in patients with COVID-19

Public title
The effect of NBS powder in treatment of patients with COVID-19

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Covid 19 positive patients with with age over 20 years
Exclusion criteria:
Disagreement of the patient or relatives to participate in the project Drug sensitivity to NBS Patient death during common and selective treatments

Age
From **20 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, simple randomization method will be used. A randomized list will be generated by online randomization site. Patients will be allocated to intervention or control group according to the generated list.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study patients and researchers don't know which group of patients will use the NBS. Physician and clinicians team know about the group who use the powder.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences

Street address
Fahmideh Street

City
Hamadan

Province
Hamadan

Postal code
6517838778

Approval date
2020-04-11, 1399/01/23

Ethics committee reference number
IR.UMSHA.REC.1399.046

Health conditions studied

1

Description of health condition studied
COVID-19 pneumonia

ICD-10 code
U07.2

ICD-10 code description
COVID-19,

Primary outcomes

1

Description
Pulmonary symptoms

Timepoint
4 weeks after intervention

Method of measurement
CT Scan

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in intervention group in addition to the standard antiviral treatment of the two-drug regimen, NBS powder will be prescribe is below: Dosage of NBS is 500 mg capsules daily in four capsules (two grams) given in divided doses of one gram in the morning and one gram in the evening for 4 weeks.

Category
Treatment - Drugs

2

Description
Control group: standard antiviral treatment of the two-drug regimen including: Hydroxychloroquine - Caltra (Lupinavir + Ritonavir)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Farid Azizi Jalilian

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Farid Azizi Jalilian
Position
Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available