

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 0548

###### Email address

salman.khazaei61@gmail.com

##### 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

**Street address**

Fahmideh Street  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
657838678  
**Phone**  
+98 81 3838 0548  
**Email**  
azizifarid@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Saeed Bashirian  
**Street address**  
Fahmideh Street  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6571838678  
**Phone**  
+98 81 3838 0717  
**Email**  
s\_bashirian@yahoo.com  
**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  
**Latest degree**

Ph.D.  
**Other areas of specialty/work**  
Virology  
**Street address**  
Fahmideh Street  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838678  
**Phone**  
+98 81 3838 0717  
**Email**  
azizifarid@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Farid Azizi Jalilian  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Virology  
**Street address**  
Fahmideh Street  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838678  
**Phone**  
+98 81 3838 0717  
**Email**  
azizifarid@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Farid Azizi Jalilian  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Virology  
**Street address**  
Fahmideh Street  
**City**  
Hamadan  
**Province**  
Hamadan

**Postal code**

6517838678

**Phone**

+98 81 3838 0717

**Email**

azizifarid@gmail.com

**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