Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of Nutrition Bio-Shield (NBS) herbal powder on inflammatory laboratory parameters and its effect on the mortality rate of patients with covid-19

Protocol summary

Study aim
Investigating the effect of Nutrition Bio-shield (NBS) herbal powder on the mortality rate of patients infected with the Covid-19 virus

Design
Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 400 patients. The RAND function of Excel software was used for randomization.

Settings and conduct
In the present study, patients, researchers, nurses and statisticians do not know about the grouping of patients who receive the NBS powder. This clinical trial will be conducted in the Farabi Hospital in Mashhad. Patients in the intervention group (200 people), in addition to receiving the routine treatment adopted by the attending physician based on the guidelines, will also receive the NBS powder for 14 days. The control group (200 people) will also receive the same treatment panel along with placebo for 14 days. Before and after the intervention, the demographic and laboratory parameters considered in this study are collected from the patients and recorded in the file. Finally, the results will be analyzed with the help of significant statistical methods.

Participants/Inclusion and exclusion criteria
In this study, patients over 20 years old whose infection with the covid-19 virus was confirmed by a specialist with clinical symptoms, computerized tomography scan and molecular methods were included in the study. On the other hand, suffering from underlying and autoimmune diseases as well as the use of immunosuppressive drugs by patients are the main criteria for not entering the study.

Intervention groups
In the intervention group, NBS powder will be prescribed 4.5 grams daily in 3 doses of 1.5 grams for 14 days along with the main treatment. The control group will receive a placebo in addition to the main treatment panel.

Main outcome variables
Duration of infection ; Mortality rate of patients ; Count of white blood cells ; Hospitalization period

General information

Reason for update

Acronym
NBS-Covid

IRCT registration information
IRCT registration number: **IRCT20230116057135N2**
Registration date: **2023-04-05, 1402/01/16**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-05, 1402/01/16**
Update count: **0**

Registration date
2023-04-05, 1402/01/16

Registrant information

Name
Mehrdad Mosadegh

Name of organization / entity

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Iran (Islamic Republic of)

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+98 935 563 3390

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Nutrition Bio-Shield (NBS) herbal powder on inflammatory laboratory parameters and its effect on the mortality rate of patients with covid-19

Public title

NBS powder effect on the mortality rate of patients with covid-19

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 20 years old Corona patients based on clinical symptoms, Computerized Tomography (CT) scan and laboratory tests such as Complete Blood Count (CBC), Erythrocyte Sedimentation Rate (ESR), C-Reactive Protein (CRP), Creatine Phosphokinase (CPK), Lactate Dehydrogenase (LDH), D-Dimer and finally Polymerase Chain Reaction (PCR) confirmation test for the presence of the infectious agent.

Exclusion criteria:

The patient's withdrawal from the study Patients with any other chronic disease such as diabetes, cardiovascular disease, etc. Patients who have received supplements of vitamin D, zinc, B vitamins and other micronutrients in the last month. Pregnant and lactating mothers Use of corticosteroids and immunosuppressive drugs Observing any drug sensitivity (especially digestive sensitivity to gluten) as determined by the attending physician Deterioration of the patient's clinical symptoms due to the consumption of NBS powder, as determined by the attending physician Patient's death during common and selective treatments (in case of death, the patient's information is fully recorded and laboratory tests are performed along with other samples to determine the possible effect of the drug on the patient's death)

Age

From **20 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **400**

More than 1 sample in each individual

Number of samples in each individual: **3**

Each time blood received from the patient is collected in tubes without anticoagulant and in the amount of 9 cc by the laboratory sampler, and its serum is received to perform the relevant tests. In the case of CBC test, 6 cc of blood is collected from the patient in tubes containing Ethylenediaminetetraacetic Acid (EDTA) anticoagulant only at the beginning and end of the study. A blood sample with sodium citrate anticoagulant is also received for ESR test.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into intervention and control groups by random block method. Allocation of the samples to two groups with random permutation block design will be two treatments with blocks of four. In this way, the letter A is considered for the intervention group and the letter B is considered for the control group. Then we write all the alternating combinations of the letters A, A, B, and B, which are 6 different combinations, on 6 cards in this order: AABB, ABBA, ABAB, BAAB, BABA, BBAA, then a digit is randomly selected from 1 to 6. and continue this process until the sample volume reaches the quorum.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients, researchers and data analysts don't know which group of patients will use the NBS. Physician and clinicians team, due to the prevention of possible side effects in order to consume this product, 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

Research Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh St., Qaem Sq.

City

Hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2023-03-04, 1401/12/13

Ethics committee reference number

IR.UMSHA.REC.1401.1043

Health conditions studied

1

Description of health condition studied
Covid-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Measurement of inflammatory factors
Timepoint
Before the start of the intervention, after the completion of the intervention
Method of measurement
Gold standard methods (ESR test by Westergren method, CRP test by Electrochemical Immunoassay method, D-Dimer test by latex rapid kit method)

2

Description
Measurement of white blood cells
Timepoint
Before the start of the intervention, after the completion of the intervention
Method of measurement
Cell Counter

Secondary outcomes

1

Description
Mortality Rate
Timepoint
After the completion of the intervention
Method of measurement
Checking the patient's vital signs

Intervention groups

1

Description
Intervention group: Patients in the intervention group, in addition to the standard treatment panel, receive Nutrition Bio-Shield (NBS) powder as follows: the amount of NBS 500 mg capsule is 4.5 g daily in three doses: 1.5 g in the Morning, 1.5 g in the Afternoon, and 1.5 g Night, 14 days.
Category
Treatment - Drugs

2

Description
Control group: In addition to the standard treatment regimen, patients in the control group also receive placebo capsules that are given in the morning, noon, and night.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital
Full name of responsible person
Dr. Manije Nezamdoost
Street address
Farabi Hospital, Kowsar St., Vakil Abad St., Mashhad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Farid Azizi Jalilian
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Hamadan University of Medical Sciences, Shahid Fahmideh St., Qaem Sq., Hamadan
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Wehrdad@gmail.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

Private

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

Tehran University of Medical Sciences

Full name of responsible person

Mehrdad Mosadegh

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

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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