Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Evaluation of the effect of a natural product called Capsule 4 of edible fungi based on Ganoderma, Lentinula edodes, Trametes versicolor, Grifola frondosa on clinical and laboratory symptoms, respiratory and prognosis of patients with coronavirus and monkeypox referred to the Infectious Diseases Clinic of Imam Reza Hospital in 2022

Protocol summary

Study aim

Evaluation of the effect of a natural product called Capsule 4 of edible fungi based on Ganoderma, Lentinula edodes, Trametes versicolor, Grifola frondosa on clinical and laboratory symptoms, respiratory and prognosis of patients with coronavirus and monkeypox referred to the Infectious Diseases Clinic of Imam Reza Hospital in 2022

Design

Clinical trial with control group, with parallel groups, double-blind, Randomized, phase 3 on 100 patients. Randomization method: random blocks were used.

Settings and conduct

100 patients are considered. Due to the difference in the severity of the disease, patients are divided into two general categories of patients hospitalized Mild and Moderate in the control and intervention group in the hospital (50 patients Moderate and 50 patients Mild hospitalized) and are evaluated separately. And one capsule a day is used by the patient for 5 days.

Participants/Inclusion and exclusion criteria

Admission for COVID-19 patients; ranging in age from 18 to 70 years old; without a medical history (diabetes, hypertension, smoking, hypertension) who has a positive PCR test and symptoms. Exclusion criteria: patients in critical condition who should be admitted to the intensive care unit; inability to continue the plan; side effects that can stop the plan or leave the subject after consumption; creating any unwanted problems including heartburn, nausea, nausea, vomiting, diarrhea, etc; create any type that uses skin, or so on.

Intervention groups

Control group: hospitalized patients receiving the protocol of the Ministry of Health. Intervention group: Inpatients receiving medication.

Main outcome variables

ESR; LDH; CBC; Ca; K; Na; CRP; Blood Sugar; Creatinin; Urea; Weakness; Nausea; Respiratory quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211020052819N1**
Registration date: **2022-07-04, 1401/04/13**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-04, 1401/04/13**
Update count: **0**

Registration date

2022-07-04, 1401/04/13

Registrant information

Name
Mozhdeh Haddadi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 6642 7293
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-25, 1401/04/04

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of a natural product called Capsule 4 of edible fungi based on Ganoderma, Lentinula edodes, Trametes versicolor, Grifola frondosa on clinical and laboratory symptoms, respiratory and prognosis of patients with coronavirus and monkeypox referred to the Infectious Diseases Clinic of Imam Reza Hospital in 2022

Public title

Evaluation of the effect of a natural product called Capsule 4 of edible fungi based on Ganoderma, Lentinula edodes, Trametes versicolor, Grifola frondosa on clinical and laboratory symptoms, respiratory and prognosis of patients with coronavirus and monkeypox referred to the Infectious Diseases Clinic of Imam Reza Hospital in 2022

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Admission for COVID-19 patients, ranging in age from 18 to 70 years, No history for diabetes, hypertension, smoking, hypertension Positive PCR test for COVID-19

Exclusion criteria:

Patients with very large lung involvement and severe general condition and should be admitted to the intensive care unit. Reluctance to continue the plan Side effects that can cause the patient to stop the plan or leave the study after taking the supplement Creating any unwanted digestive problems including heartburn, nausea, nausea, vomiting, diarrhea, etc. Any allergies, whether skin, respiratory or other Creating any side effects that did not exist before taking the supplement

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Describe how to randomize To perform the method, random presentation (random blocks) should be used for implementation using Randome Allocation software. How to do it so that equal to the total number of patients, the sheet is considered to be divided into four equal groups and in a specific part of the top of the sheet to separate and categorize information use the letters S and I. S; Standard I: Intervention Now, with each patient's visit, we randomly remove a sheet from the drawer and give it to one of the two groups (intervention or control). Once the 4 sheets have been pulled out, completed, and returned to the drawer, we can continue this procedure until the end of the number of patients intended to complete the trial.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant, Outcome assessor, Data analyser, Data and Safety Monitoring Board are masked.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Army University of Medical Sciences

Street address

Etemadzadeh St, Fatemi St

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Province

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Postal code

1411718541

Approval date

2022-06-19, 1401/03/29

Ethics committee reference number

IR.AJAUMS.REC.1401.032

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

RA01.0

ICD-10 code description

Severe Acute Respiratory Syndrome coronavirus

Primary outcomes

1

Description

LDH

Timepoint
Before the intervention and 5 days after the intervention
Method of measurement
blood test

2

Description
CBC diff
Timepoint
Before the intervention and 5 days after the intervention
Method of measurement
blood test

3

Description
Na/ k/ Ca / SGOT / SGPT / Creatine / FBS/ Urea
Timepoint
Before the intervention and 5 days after the intervention
Method of measurement
blood test

4

Description
ESR1
Timepoint
Before the intervention and 5 days after the intervention
Method of measurement
blood test

5

Description
CRP
Timepoint
Before the intervention and 5 days after the intervention
Method of measurement
blood test

6

Description
Weakness and nausea
Timepoint
Before the intervention and 5 days after the intervention
Method of measurement
check list

Secondary outcomes

1

Description
Determining the effect of supplementation on the amount of oxygen
Timepoint
5 Days
Method of measurement
Pulse oximeter

2

Description
General condition of people and vitality after treatment
Timepoint
5 Days
Method of measurement
En Examination and history

Intervention groups

1

Description
This study will be conducted as a three-blind randomized clinical trial for 5 days on 100 people infected with corona virus. For this purpose, 50 mild patients and 50 moderate hospitalized patients (a total of 100 patients) who have already been diagnosed with COVID-19 and monkey pox based on pulmonary involvement or positive PCR will be randomly divided into two groups (25 patients Mild along with 25 moderate patients hospitalized in the intervention group and 25 mild patients along with 25 moderate patients hospitalized in the control group). intervention group; Daily one capsule (each capsule containing 200 mg of the combination of 4 mushrooms). Supplements and placebo will be received after breakfast. For data analysis, SPSS version 22 software will be used to analyze data with a significance level of $P<0.05$.
Category
Treatment - Drugs

2

Description
Control group: 50 patients receiving the protocol of the Ministry of Health, the control group will take a placebo capsule (200 mg of maltodextrin in each capsule) daily for 5 days. 25 mild patients along with 25 moderate patients hospitalized in the control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital, 501 Army of the Islamic Republic Iran
Full name of responsible person
Dr. Alireza Dadashi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Artesh University of Medical Sciences
Proportion provided by this source
10
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
Artesh University of Medical Sciences
Full name of responsible person
Mozhdeh Haddadi
Position
Researcher
Latest degree
Master
Other areas of specialty/work
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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
No - There is not a plan to make this available
Title and more details about the data/document
Information will be considered in the publication of the article
When the data will become available and for how long
One year after the results are published
To whom data/document is available
University professors
Under which criteria data/document could be used
Researchers will have access after the article is published
From where data/document is obtainable
https://www.linkedin.com/in/mozhdehhaddadi/
https://www.researchgate.net/profile/Mozhdeh-Haddadi
What processes are involved for a request to access data/document
Sending direct messages will have access to the specialized pages of LinkedIn and Research Gate
Comments