

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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, 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)

Phone

+98 21 6642 7293

Email address

m.haddadi@modares.ac.ir

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, 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 Random 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

Etamadzadeh St, Fatemi St

City

Tehran

Province

Tehran

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

Street address

Etemadzadeh St, Fatemi St

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

drdadashialireza@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Dr. Reza Mosead Ronkiani

Street address

Etemadzadeh St, Fatemi St

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6001

Email

reza.mosaed@ajaums.ac.ir

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

Biochemistry

Street address

Gordafarid St, Etemadzadeh St, Fatemi St

City

Tehran

Province

Tehran

Postal code

1411845117

Phone

+98 21 6642 7293

Email

mozhdeh_haddadi_777@yahoo.com

Person responsible for scientific 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

Biochemistry

Street address

Gordafarid St, Etemadzadeh St, Fatemi St

City

Tehran

Province

Tehran

Postal code

1411845117

Phone

+98 21 6642 7293

Email

mozhdeh_haddadi_777@yahoo.com

Person responsible for updating data

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

Biochemistry

Street address

Gordafarid St, Etemadzadeh St, Fatemi St

City

Tehran

Province

Tehran

Postal code

1411845117

Phone

+98 21 6642 7293

Email

mozhdeh_haddadi_777@yahoo.com

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