

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of a natural product called 4 capsule plant based on Malus Domestica, Nigella Sativa, Peganum harmala, Terminalia chebula and vitamin C on clinical and laboratory, respiratory and prognostic symptoms of patients with Covid-19 virus

Protocol summary

Study aim

Evaluation of the effect of a natural product called 4 capsule plant based on Malus Domestica, Nigella Sativa, Peganum harmala, Terminalia chebula and vitamin C on clinical and laboratory, respiratory and prognostic symptoms of patients with Covid-19 virus referred to the clinic Infection of Imam Reza Hospital in 1400

Design

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 for 5 days, one capsule per day is used by the patient.

Settings and conduct

Infectious Diseases Clinic of Imam Reza Hospital 501 Army

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: Hospitalized patients receiving medication

Main outcome variables

LDH / CBC / Ca / K / Na / CRP / Sugar / Creatine / Urea / Weakness / Nausea / Age / Gender/Respiratory quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211020052819N2**

Registration date: **2022-07-11, 1401/04/20**

Registration timing: **retrospective**

Last update: **2022-07-11, 1401/04/20**

Update count: **0**

Registration date

2022-07-11, 1401/04/20

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

2021-09-15, 1400/06/24

Expected recruitment end date

2022-03-20, 1400/12/29

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 4 capsule plant based on Malus Domestica, Nigella Sativa, Peganum harmala, Terminalia chebula and vitamin C on clinical and laboratory, respiratory and prognostic symptoms of patients with Covid-19 virus

Public title

Evaluation of the effect of a natural product called 4 capsule plant based on Malus Domestica, Nigella Sativa, Peganum harmala, Terminalia chebula and vitamin C on clinical and laboratory, respiratory and prognostic symptoms of patients with Covid-19 virus referred to the clinic Infection of Imam Reza Hospital in 1400

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Admission for Covid patients, ranging in age from 18 to 70 years without underlying disease (diabetes, hypertension, smoking, hyperlipidemia) 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

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

2021-09-08, 1400/06/17

Ethics committee reference number

IR.AJAUMS.REC.1400.135

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

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 (100 people in total) who have already been diagnosed with COVID-19 based on pulmonary involvement or positive PCR will be randomly divided into two groups (25 mild patients with 25 moderate patients hospitalized in the intervention group and 25 mild patients along with 25 moderate patients hospitalized in the control group).

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

Full name of responsible person

Dr. Maryam Dadmanesh

Street address

Etemadzadeh St, Fatemi St

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1411718541

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+98 912 297 7305

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr. Reza Mosead Ronkiani

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Army 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

Mahdiar Taghdisi Hadipour

Position

Researcher

Latest degree

Bachelor

Other areas of specialty/work

Computer Engineering

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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

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Person responsible for updating data

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

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Position

Faculty physician

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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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
published 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