

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Determining the Safety and Effectiveness of ENDOR Oral Combination Drug in the Treatment of Patients with Covid-19 Referred to Imam Khomeini Hospital in Tehran

Protocol summary

Study aim

Determination of Effectiveness and safety of Endor oral drug in patients diagnosed with COVID19

Design

Clinical trial with control group, single blind, randomized based on Simple Randomization on 200 patients

Settings and conduct

Patients hospitalized in Imam Khomeini Hospital who meet the inclusion criteria will be treated with Endor or placebo along with standard treatment according to national protocol for 7 days. This is the single blind study and Patients do not know which group (control or intervention) they are in.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: COVID-19 positive test Confirmed CT scan Over 18 years old Individuals experienced Acute respiratory distress syndrome (ARDS) and Myocarditis
Exclusion Criteria: Substance and alcohol consumers Consumers of immunosuppressive drugs People undergoing chemotherapy, radiotherapy and interferon Consumers of growth hormone drugs, testosterone and anabolic steroids

Intervention groups

Control group: people taking placebo + treatment according to national protocol Intervention group: People taking Endor + treatment according to national protocol

Main outcome variables

Clinical Presentation; Radiological findings; Laboratory findings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100601004076N26**
Registration date: **2021-10-23, 1400/08/01**

Registration timing: **prospective**

Last update: **2021-10-23, 1400/08/01**

Update count: **0**

Registration date

2021-10-23, 1400/08/01

Registrant information

Name

Minoos Mohraz

Name of organization / entity

Iranian Research Center for HIV/AIDS, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 7984

Email address

minoomohraz@ams.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the Safety and Effectiveness of ENDOR Oral Combination Drug in the Treatment of Patients with Covid-19 Referred to Imam Khomeini Hospital in Tehran

Public title

Determining the Safety and Effectiveness of ENDOR Oral Combination Drug in the Treatment of Patients with Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed and voluntary oral and written consent of the patient or his / her guardian to participate in the study
Age over 18 years SARS-CoV-2 virus PCR test positive or having one of the following conditions: Strong symptoms of COVID-19 disease, including fever, dry cough, and shortness of breath Existence of CT scan confirming lung involvement, especially ground glass view

Exclusion criteria:

Individuals whose Covid-19 test has not been approved
Individuals who use drugs
Individuals who drink alcohol
Individuals who use immunosuppressive drugs
Individuals under chemotherapy or radiotherapy
Individuals who use growth hormone, testosterone and anabolic steroids

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method is used. Random number table is a set of numbers that are generated completely randomly and are tabulated. Firstly, we determine the direction of the random number table and then we decide to read the random number table from above. Then we consider even numbers for the intervention group and odd numbers for the control group. We assign 200 codes from 1 to 200 to the patients hospitalized to the ward. Then we put patients with even code in the intervention group and patients with odd code in the control group. Thus, a total of 200 people will be assigned to the intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

For reducing the bias, single-blind method was taken into account. Placebo capsules were used to prevent patients from being informed about which group they are belonging to, Control or Intervention. Placebo capsules are designed to be similar in color and size to Endor capsules. In this study, patients will not be aware of which group they are in, the rest of the study members are aware of patients grouping.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Iranin Research Center for HIV/AIDS, Qarib street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.676

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes**1****Description**

Complete Blood Count (CBC), Differentiation

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Laboratory Tests

2**Description**

Erythrocyte sedimentation rate (ESR)

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Laboratory Test

3

Description

C-Reactive Protein (CRP)

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Laboratory Test

4

Description

Alanine Aminotransferase (ALT)

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Laboratory Test

5

Description

Aspartate aminotransferase (AST)

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Laboratory Test

6

Description

Creatinine

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Laboratory Tests

7

Description

Di-Dimer Test

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Laboratory Tests

8

Description

Respiratory Presentations

Timepoint

During Hospitalization

Method of measurement

Clinical Examination

9

Description

Weakness and lethargy

Timepoint

During Hospitalizations

Method of measurement

Clinical Examinations

10

Description

Fever

Timepoint

During Hospitalization

Method of measurement

Clinical Presentations

11

Description

Myalgia

Timepoint

During Hospitalization

Method of measurement

Clinical Examinations

12

Description

Dry Cough

Timepoint

During Hospitalization

Method of measurement

Clinical Examinations

13

Description

Existence of sputum

Timepoint

During Hospitalization

Method of measurement

Clinical Examinations

14

Description

Sore throat

Timepoint

During Hospitalization

Method of measurement

Clinical Examinations

15

Description

Diarrhea

Timepoint

During Hospitalization

Method of measurement

Clinical Examinations

16

Description

Shortness of breath

Timepoint

During Hospitalization

Method of measurement

Clinical Examination

17

Description

Rhinitis

Timepoint

During Hospitalization

Method of measurement

Clinical Examinations

18

Description

Nausea

Timepoint

During Hospitalization

Method of measurement

Clinical Examinations

19

Description

Headache

Timepoint

During Hospitalization

Method of measurement

Clinical Examinations

20

Description

Shivering

Timepoint

During Hospitalization

Method of measurement

Clinical Examination

21

Description

Presence of ground-glass appearance

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Chest X-ray

22

Description

Alveolar Complication

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Chest X-ray

23

Description

Unilateral or bilateral pulmonary involvement

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Chest X-ray

24

Description

Location of Involvement

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Chest X-ray

25

Description

Presence of Acute respiratory distress syndrome (ARDS)

Timepoint

During Three days of Hospitalization and at the time of discharging

Method of measurement

Chest X-ray

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the intervention group, in addition to the standard treatment according to national protocol, consumes two oral capsules of Endor every eight hours for seven days. This capsule contains Betacarotene -2.5mg, Curcuma longa rhizome extract equiv. to dry- 1.25g, (Equiv. Curcumin- 23.75mg), Fish Oil – Rich in Omega 3 acids- 250mg, (Equiv. Docosahexaenoic acid [DHA]-30mg), (Equiv. Eicosapentaenoic acid [EPA]- 45mg), (Equiv. Omega 3 marine triglycerides-75mg), Sodium ascorbate-56.8mg, (Equiv. Ascorbic acid [Vitamin C]-50mg), Wheatgerm Oil – 75mg, Zinc Sulfate – 27.62mg, (Equiv. Zinc – 10mg). This capsule has been manufactured by Ghadiminezhad Daru

Category

Treatment - Drugs

2

Description

Control group: Treatment based on National Protocol

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Minoo Mohraz

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Imam Khomeini hospital, Dr Qarib st., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghadiminezhad Daru

Full name of responsible person

Iraj Ghadiminejad

Street address

Department 7, First Floor, Jahan-E Felez Building, No. 7, Masjed-E Aqa Alley, Pamenar St, 15-E khodad St, Tehran, Iran

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Web page address

<https://gnpau.com/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ghadiminezhad Daru

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**

Persons

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

SeyedAhmad SeyedAlinaghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Clinical Epidemiology

Street address

End of Keshavar Blvd - Imam Khomeini Hospital Complex- Basement of the Infection department (Building 6) - Iranian Research Center for HIV/AIDS

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Minoo Mohraz

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

SayedAhmad SeyedAlinaghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Clinical Epidemiology

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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