

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

**Street address**

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

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Tehran

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**Postal code**

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**Email**

minoomohraz@gmail.com

## 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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**Phone**

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iraj@gnpau.com

**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

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**Full name of responsible person**

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Specialist

**Other areas of specialty/work**

Infectious diseases

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Clinical Epidemiology

**Street address**

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s\_a\_alinaghi@yahoo.com

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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