Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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
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Name of organization / entity
Iranian Research Center for HIV/AIDS, Tehran University of Medical Sciences
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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 Aminotransferease (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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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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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

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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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SeyedAhmad SeyedAlinaghi

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Associate Professor

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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