Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the Safety and Effectiveness of Septimeb in Patients with COVID-19 Referred to Selected Hospitals of Tehran University of Medical Sciences: A Clinical Trial Study (Phase III)

Protocol summary

Study aim
valuating the Safety and Effectiveness of Septimeb in Patients with COVID-19

Design
Clinical trial with control group, without blinding, randomized by simple randomization on 240 patients

Settings and conduct
Patients admitted to Imam Khomeini, Shariati, Amir-E-Alam and Ziaian hospitals who meet the inclusion criteria will be treated with Septimeb for a minimum of seven days and a maximum of 14 days in addition to the national protocol. People in the control group are treated only according to the national protocol. There is no blindness in this study and patients are aware of which group (control or intervention) they are in.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 18 years old, having positive PCR test, fever, dry cough, shortness of breath, CT scan with at least 40% lung involvement, presence of myocarditis, sepsis, ARDS, cytokine storm, increased ESR, increased LDH and increased D-DIMER test Exclusion Criteria: No COVID-19 PCR test Drug users - Alcohol consumers and Immune suppressive drug users People undergoing chemotherapy Consumers of growth medications, testosterone and anabolic steroids Patients during pregnancy and breastfeeding

Intervention groups
Control group: treatment according to national protocol (including corticosteroids) Intervention group: Septimeb treatment + national protocol treatment (including corticosteroids)

Main outcome variables
Patients' Mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100601004076N27**
Registration date: **2022-01-02, 1400/10/12**
Registration timing: **prospective**

Last update: **2022-01-02, 1400/10/12**
Update count: **0**

Registration date
2022-01-02, 1400/10/12

Registrant information

Name
Minoo Mohraz
Name of organization / entity
Iranian Research Center for HIV/AIDS, Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Safety and Effectiveness of Septimeb in Patients with COVID-19 Referred to Selected Hospitals of Tehran University of Medical Sciences: A Clinical Trial Study (Phase III)

Public title
Evaluating the Safety and Effectiveness of Septimeb in 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 CT scan (HRCT or Spiral CT) that shows involvement with Cornavirus (at least 40% of lung involvement), especially ground glass in the peripheral or base of the lungs Patients suffering from life-threatening complications due to COVID-19 disease including ARDS, myocarditis, sepsis, cytokine storm (with ESR above 100 or platelet decline over 3 days or elevated D-Dimer above normal or LDH above normal).

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 The patient is pregnant or breastfeeding.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **240**

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 240 codes from 1 to 240 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 240 people will be assigned to the intervention and control groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not 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
2021-12-12, 1400/09/21

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1052

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
Morbidity

Timepoint
At the time of hospitalization, every 3 days until the day of discharge from the hospital

Method of measurement
Vital Signs Examination

Secondary outcomes

1

Description

Fever

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

2

Description

Headache

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

3

Description

Nausea

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

4

Description

Shivering

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

5

Description

Rhinitis

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

6

Description

Dry Cough

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

7

Description

Myalgia

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

8

Description

Diarrhea

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

9

Description

Shortness of breath

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

10

Description

Weakness and lethargy

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

11

Description

Blood Pressure

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

12

Description

O2 saturation rate

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Clinical Examination

13

Description

Complete blood count and differentiation

Timepoint

At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge

Method of measurement

Laboratory Test

14

Description
C-reactive Protein
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Laboratory Test

15

Description
Erythrocyte sedimentation rate (ESR)
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Laboratory Test

16

Description
Alanine Aminotransferease (ALT)
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Laboratory Test

17

Description
Aspartate aminotransferase (AST)
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Laboratory Test

18

Description
Creatinine Test
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Laboratory Test

19

Description
Di-Dimer Test
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Laboratory test

20

Description
Presence of ground-glass appearance
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Chest X-ray

21

Description
Alveolar Complication
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Chest X-ray

22

Description
Unilateral or bilateral pulmonary involvement
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Chest X-ray

23

Description
Location of Involvement
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Chest X-ray

24

Description
Presence of Acute respiratory distress syndrome (ARDS)
Timepoint
At the time of hospitalization, every three days until respiratory conditions stabilize, at the time of discharge
Method of measurement
Chest X-ray

Intervention groups

1

Description
Intervention group: Patients will receive 10 ml (150 mg) of Septimib at the first day and 20 ml (30 mg) from the second day (minimum for one week and maximum for two weeks) in addition to national protocol treatments (including corticosteroids).
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
Dr. Mohammad Reza Salehi
Street address
Imam Khomeini hospital, Dr. Qarib st., Tehran, Iran
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Province
Tehran
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Phone
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Imamhospital@tums.ac.ir

2

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Naser Aghdam
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Jalale-Ale-Ahmad Ave, North Karegar Ave.
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Postal code
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Phone
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shariatihosp@tums.ac.ir

3

Recruitment center
Name of recruitment center
Ziaeian Hospital
Full name of responsible person
Saeid Reza Jamali Moghaddam
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Qazvin street, Qapan crossroads
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Phone
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4

Recruitment center
Name of recruitment center
Amir A'lam Hospital
Full name of responsible person
Alo Asadollahi Amin
Street address
North Sa'di St., Enghelab Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
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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
Tehran University of Medical Sciences
Proportion provided by this source
100
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
University of social welfare and rehabilitation sciences

Full name of responsible person
Hamidreza Khorram Khorshid

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Genetics

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Associate Professor

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Researcher

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Master

Other areas of specialty/work
Immunology

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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