

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Sep 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

Country

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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 Coronavirus (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

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

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Province

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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 Aminotransferase (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

Email

ziaeian@tums.ac.ir

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Dr. Mohammad Reza Salehi

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

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Email

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2**Recruitment center****Name of recruitment center**

Shariati Hospital

Full name of responsible person

Naser Aghdam

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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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4**Recruitment center****Name of recruitment center**

Amir A'lam Hospital

Full name of responsible person

Alo Asadollahi Amin

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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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Vice Chancellor of Research, Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd.

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Associate Professor

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Epidemiology

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Person responsible for updating data

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Researcher

Latest degree

Master

Other areas of specialty/work

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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