Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Study the Efficacy and Safety of SeptimebTM in the Treatment of COVID-19 Infection in Iranian Patients: A Clinical Trial (Case Series)

Protocol summary

Study aim

In this research project, we are intending to study the efficacy of SeptimebTM in the management of COVID-19.

Design

This is a single arm, with no control group, not blinded and randomized phase II clinical trial, in which the participants (30 individuals) in addition to standard treatment (if available) will receive Septimeb as well.

Settings and conduct

Patients in intervention group who suffer from sever (ARDS patients who are not admitted in ICU) or very severe (ARDS or related symptoms and signs who are admitted in ICU) complications of COVID-19, will receive septimeb (infusion) for up to 14 days.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 18-65 years Known case of Covid-19 by relative signs, symptoms, Lab., radiology and CT scan Data. Existence of severe symptoms and signs of the disease. Not taking any immunstimulators during last three months. Completed consent form by the patients or guardians. Exclusion criteria: Recent drug abuse or alcohol consumption. Taking growth hormone, testosterone or anabolic steroids during last 30 days. Long term use of immunosuppressives, Chemotherapy, treatment by interferon or radiotherapy during last 3 weeks. Pregnancy or breast feeding Positive symptoms for common cold or positive PCR result for influenza (but not confirmed COVID-19).

Intervention groups

Patients who suffer from sever (ARDS patients who are not admitted in ICU) or very severe (ARDS or related symptoms and signs who are admitted in ICU) complications of COVID-19, receive 150 mg of Septimeb in 500 ml of DW 5%, infused over 1.5 hours on the first day. In absence of the complications, the treatment is continued for up to 14 days with 300 mg daily.

Main outcome variables

 Number of admission days The mortality rate in COVID-19 patients The potential side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200324046847N1**
Registration date: **2020-03-31, 1399/01/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-31, 1399/01/12**
Update count: **0**

Registration date

2020-03-31, 1399/01/12

Registrant information

Name

Hamidreza Khorram Khorshid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0138

Email address

hrkk1@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-28, 1399/01/09

Expected recruitment end date

2020-04-29, 1399/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the Efficacy and Safety of SeptimebTM in the Treatment of COVID-19 Infection in Iranian Patients: A Clinical Trial (Case Series)

Public title
Treatment of patients with Corona virus infection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-65 years Known case of Covid-19 by relative signs, symptoms, Lab. radiology and CT scan Data Existence of Severe symptoms and signs of the disease (infection by COVID-19) Not taking any immunstimulators during last three months. Completed consent form by the patients or guardians
Exclusion criteria:
Recent drug abuse or alcohol consumption. Taking growth hormone, testosterone or anabolic steroids during last 30 days. Long term use of immunosuppressives. Chemotherapy, treatment by interferon or radiotherapy during last 3 weeks• Pregnancy or breast feeding Positive symptoms for common cold or positive PCR result for influenza but not confirmed COVID-19
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
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
Central organization of Tehran University of Medical Sciences, Six floor, Qods St. Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2020-03-25, 1399/01/06
Ethics committee reference number
IR.TUMS.VCR.REC.1399.041

Health conditions studied

1

Description of health condition studied
Infection caused by COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified' is assigned to a disease diagnosis of COVID-19 confirmed by laboratory testing

Primary outcomes

1

Description
Number of admission days
Timepoint
every day
Method of measurement
Number of days

2

Description
The mortality rate in COVID-19 patients
Timepoint
Everyday
Method of measurement
Number of death

3

Description
Assessment of potential side effects
Timepoint
Every day
Method of measurement
Inspection for potential side effects

Secondary outcomes

1

Description
symptoms including coughing, fever, respiratory distress, etc
Timepoint
Every day
Method of measurement

By inspection and assessment of patients

2

Description
It is defined by the test results for: Blood gases, CBC, WBC, lymphocyte and Platelet counts; Coagulation testing; measurement of electrolytes; liver and renal function tests; CRP, LDH, Creatine kinase
Timepoint
At least every three days
Method of measurement
Measurements of Blood gases and Blood indices

3

Description
Performing radiologic and CT scan
Timepoint
At lease at the admission and discharge of patients
Method of measurement
Using radiology and CT scan equipments

Intervention groups

1

Description
Intervention group: Patients who suffer from sever (ARDS patients who are not admitted in ICU) or very severe (ARDS or related symptoms and signs who are admitted in ICU) complications of COVID-19, received 150 mg of SeptimebTM in 500 ml of DW 5%, infused over 1.5 hours on the first day. All hemodynamic data are monitored during the infusion and in case of any negative hemodynamic deterioration, dermal rash, urticaria or anaphylactic reaction, the infusion discontinued. In absence of the mentioned complications the treatment is continued by administration of 300 mg of the drug that will be infused in 500 ml of DW5%, every day for up to 14 days (the duration of treatment will be adjusted based on the severity of symptom and sign of the patients).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital (Complex)
Full name of responsible person
Minoo Mohraz
Street address
Dr. Gharib Street, at the end Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6694 7984
Email
minoomohraz@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
No. 226, Six Floor., Qods St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1416753955
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir
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
30
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

2

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Dr. Mohammadreza Khodaie -Ardakani
Street address
Kodakyar Ave., Daneshjo Blvd., Evin
City
Tehran
Province
Tehran
Postal code
1985713871
Phone

+98 21 2218 0092

Fax

Email

Kh.ardakani@uswr.ac.ir

Web page address

http://www.uswr.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

70

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

Street address

Kodakyar Ave., Daneshjo Blvd., Evin

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Postal code

1985713871

Phone

+98 21 2218 0138

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hrkk1@uswr.ac.ir

Person responsible for scientific 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 updating data

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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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

After ending the study, we are going to submit the result to official organization and share with other investigator who are interested to know about the final results.

When the data will become available and for how long

Starting 6 months after publication.

To whom data/document is available

Our data will be available for people working in academic institutions and people working in businesses can also apply to receive it.

Under which criteria data/document could be used

The applicants of data should determine the type of usage (the data). After approval by the corresponding individuals, they can use the data for the mentioned purposes.

From where data/document is obtainable

The can have access to requested data through Dr. Hamidreza Khorram Khorshid using his e-mail (hrkk1@uswr.ac.ir).

What processes are involved for a request to access data/document

After formal (written or by e-mail) request and approval by the chief investigators, it will take maximum 1 month to send the requested documents.

Comments