

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Mesenchymal stem cell utilization in reducing complications and enhancing pneumonia healing in patients infected with 2019-nCoV (phase I clinical trial)

Protocol summary

Study aim

Evaluation of mesenchymal stem cell therapy in the treatment of patients with COVID-19 disease

Design

Experimental: Mesenchymal Stem Cells (MSC)
Treatment Group Conventional treatment plus MSCs
Participants will receive conventional treatment plus 3 times of MSCs(7.0×10^7 MSCs intravenously at Day 0, Day 3, Day 6)., 5 patients, clinical trial phase I
Intervention: Conventional Control Group Without MSCs
Therapy but conventional treatment should be received.

Settings and conduct

Place of study and treatment of hospitalized patients in Baqiyatallah Hospital. After validation of Criteria with Mesenchymal Stem Cell Therapy was performed on days 0, 3 and 6. The Therapist physician and the researcher are different.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Blood oxygenation saturation $< 93\%$
2. Abnormal lung CT scan 3. Significant shortness of breath 4. Fever 5. Not improving in the next 48 hours 6. There is no possibility of discharge of patient in the next 48 hours 7. Patient consent
Exclusion criteria 1. The patient should not be connected to a ventilator . 2. The patient has not given consent.

Intervention groups

Patients with confirmed COVID-19 disease

Main outcome variables

mortality rate; duration of hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200325046860N2**
Registration date: **2020-04-01, 1399/01/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-01, 1399/01/13**

Update count: **0**

Registration date

2020-04-01, 1399/01/13

Registrant information

Name

Hassan Abolghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 3166

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-28, 1399/01/09

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

2020-03-28, 1399/01/09

Actual recruitment end date

2020-04-18, 1399/01/30

Trial completion date

2020-04-29, 1399/02/10

Scientific title

Mesenchymal stem cell utilization in reducing complications and enhancing pneumonia healing in patients infected with 2019-nCoV (phase I clinical trial)

Public title

Mesenchymal Stem Cell therapy in COVID19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male or female, aged at 18 years (including) -70 years old Laboratory confirmation of 2019-nCoV infection by reverse-transcription polymerase chain reaction (RT-PCR) from any diagnostic sampling source Pneumonia that is judged by chest radiograph or computed tomography. Resp rate> 30, o2 sat < 93%,

Exclusion criteria:

Pregnancy, lactation Patients with malignant tumor, other serious systemic diseases and psychosis Patients who are participating in other clinical trials; Inability to provide informed consent Co-Infection of HIV, tuberculosis, influenza virus

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **5**

More than 1 sample in each individual

Number of samples in each individual: **5**

2019 Novel Coronavirus Pneumonia

Actual sample size reached: **5**

More than 1 sample in each individual

Actual sample size in each individual: **5**

2019 Novel Coronavirus Pneumonia

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Baqiatallah university of medical sciences

Street address

Hemmat HW, sheikh bahaaei

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-03-26, 1399/01/07

Ethics committee reference number

IR.BMSU.REC.1399.007

Health conditions studied**1****Description of health condition studied**

COVID-19 Disease

ICD-10 code

U07.02

ICD-10 code description

COVID-19 Disease

Primary outcomes**1****Description**

respiratory function of patients

Timepoint

Every 24 hours after MSC infusion

Method of measurement

Clinical, lab test , CT scan

Secondary outcomes

empty

Intervention groups**1****Description**

Treatment group: Patients with confirmed COVID-19 infection who in addition to their current treatment will be infused with 70 million mesenchymal stem cell day 0, 3 6 , infusion time 30 min 4.

Category

Treatment - Other

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

Baqiatallah general hospital

Full name of responsible person

Hasan Abolghasemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Baqiatallah university of medical sciences, HORCSCT
Proportion provided by this source
50
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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Hasan Abolghasemi
Position
Professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

make this available

Title and more details about the data/document

Clinical finding, lab test result, CT scan report,

When the data will become available and for how long

2 months after complete data

To whom data/document is available

Scientists, researcher

Under which criteria data/document could be used

All data sharing

From where data/document is obtainable

Hassan Abolghasmi via phone no. Or email

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

Contact

Comments