

# 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\*10E7 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

h.abolghasemi.ha@gmail.com

##### 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

**Street address**

Hemmat HW, sheikh Bahaaei st

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371  
**Phone**  
+98 21 8126 3791  
**Email**  
h.abolghasemi.ha@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Bagheiat-allah University of Medical Sciences  
**Full name of responsible person**  
Hasan Abolghasemi  
**Street address**  
Hemmat HW, sheikh Bahaaei st  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1435915371  
**Phone**  
+98 21 8126 3791  
**Email**  
h.abolghasemi.ha@gmail.com  
**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**  
Subspecialist  
**Other areas of specialty/work**  
Hematology  
**Street address**  
Hemmat HW, sheikh bahaaei  
**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
1435916451  
**Phone**  
+98 21 8126 3799  
**Email**  
h.abolghasemi.ha@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Bagheiat-allah University of Medical Sciences  
**Full name of responsible person**  
Hasan abolghasemi  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Hematology  
**Street address**  
Hemmat HW , sheikh bahaaei  
**City**  
Tehra  
**Province**  
Tehran  
**Postal code**  
1435916471  
**Phone**  
+98 21 8126 3791  
**Email**  
h.abolghasemi.ha@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Bagheiat-allah University of Medical Sciences  
**Full name of responsible person**  
Hasan Abolghasemi  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Hematology  
**Street address**  
Hemmat Hw, sheikh bahaaei  
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Tehran  
**Province**  
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**Postal code**  
1435916471  
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+98 21 8126 2799  
**Email**  
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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