# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Clinical trial study of safety and efficacy assessment of human umbilical cord matrix mesenchymal stem cell infusion on the treatment of new coronavirus 2019 pneumonia in humans

## Protocol summary

**Study aim**

The purpose of this study is to evaluate the safety, efficacy, and dose determination of human umbilical cord matrix-derived mesenchymal stem cell injection in the treatment of new COVID-19 pneumonia in humans. The main aim is to decrease mortality.

**Design**

This study is a parallel randomized controlled clinical trial study design. The sample size of the study is 60 COVID-19 patients that are assigned to intervention and control groups using a simple randomization method.

**Settings and conduct**

This study is performed to decrease the mortality and other complications of patients with COVID-19 and normalize blood Parameters and chest CT scan at the hospital. Included and admitted patients in infectious and intensive care units, are followed up for up to 28 days for the intended outcome after receiving the intervention.

**Participants/Inclusion and exclusion criteria**

Patients with an acute form of COVID-19 infection who are confirmed by RT-PCR and HRCT are included. Any confirmed pregnancy, ARDS with other reasons, active cancerous disease, hematological disorders, heart failure, viral disease, acquired or inherited immune deficiency, and mental illness are excluded.

**Intervention groups**

Patients in the intervention group are injected with an initial dose of 0.5 -1 million/ kg of MSC. This process is repeated 3- 4 times. This intervention is supplemented with other treatments. The control group is received standard viral treatment along with placebo (normal saline) instead of the intervention.

**Main outcome variables**

Death, FIO2, Interleukin profile, Pneumonia severity index, Oxygen Saturation index, Procalcitonin, C reactive protein, Lymphocyte count, CD3 +, CD4 +, and CD8 + T cells count, improved pneumonia using CT scan.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20211012052743N1**
Registration date: **2021-11-06, 1400/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-06, 1400/08/15**
Update count: **0**

**Registration date**

2021-11-06, 1400/08/15

**Registrant information**

**Name**

Aliasghar Rezaei

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 8819 2932

**Email address**

rezaei690@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-11-06, 1400/08/15

**Expected recruitment end date**

2022-11-22, 1401/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Clinical trial study of safety and efficacy assessment of human umbilical cord matrix mesenchymal stem cell infusion on the treatment of new coronavirus 2019 pneumonia in humans

**Public title**
Stem cell therapy for COVID-19

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients in the acute phase with Laboratory confirmation of SARS-COV-2 infection with RT-PCR Pneumonia confirmed by chest x-ray or Computed tomography Scan Respiratory rate> 30 times/minute Oxygen Saturation less than 93% Arterial oxygen partial pressure (Pao2) /oxygen inhalation(Fio2) less than 300 mm Hg No history of tumor or malignant disease CRP greater than normal range

**Exclusion criteria:**
Pregnant patient with a positive pregnancy test or during lactation or who is planning to become pregnant during the study The definitive history of acquired or inherited immune deficiency diseases The definitive psychotic illness, A history of serious mental illness or a history of suicide. Any active or treated Cancerous diseases. Creatinine greater than 1.7 mg/dL Co-infection of human immunodeficiency viruses, Hepatitis B, Hepatitis C and Human T-lymphotropic virus Any cardiac hemodynamic disorder Positive PPD test Positive syphilis test Treatment with cytotoxic drugs one month prior study

**Age**
From **18 years** old to **85 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
We use a randomization method to minimize the researchers' opinions to select participation in study groups to control bias. After selection, participants are assigned to the groups using a simple randomization method for received intervention and placebo in each participant. The randomization process is performed using Random Allocation software, and since this study consists of two groups, the allocation outputs of the participants are identified by A and B so assign of each patient in each group is unpredictable to other members of the research team. We do not notify the team manager after selecting each patient and they send out each patient's intervention type based on the software output, without the knowledge of other team members. Only the clinical care is aware of any patient's intervention in cases where the patient's condition is inappropriate.

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**
After selecting each patient to the study, the patients are selected based on the randomization output is taken from the randomization software and matching it with the patient number of the intervention in such a way that each patient, investigator, outcome assessor, and data analyzer does not determine the type of intervention the patients receive. Blinding in this study is triple blind. To maintain the blindness of the study the injection shape and color of the placebo are similar to the main intervention so that patients, physicians, and staff who evaluating the outcomes are blind to the participant's interventions to minimize the bias in outcome measurement.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committees of Avicenna Research Institute

**Street address**
Avicenna Research Institute, Shahid Beheshti University, Darakeh Street

**City**
Tehran

**Province**
Tehran

**Postal code**
1984737384

**Approval date**
2021-08-24, 1400/06/02

**Ethics committee reference number**
IR.ACECR.AVICENNA.REC.1400.018

## Health conditions studied

### 1

**Description of health condition studied**
COVID-19 disease

**ICD-10 code**
U07.01

**ICD-10 code description**
COVID-19 disease

## Primary outcomes

### 1

**Description**
Death
**Timepoint**
Up to 28 days after starting the study
**Method of measurement**
Patient observation and evaluation of vital signs

## Secondary outcomes

### 1

**Description**
Evaluation of Pneumonia Severity Index
**Timepoint**
Up to 28 days
**Method of measurement**
The PSI/PORT score

### 2

**Description**
Evaluation of oxygen supply index
**Timepoint**
Discharge from ICU
**Method of measurement**
Pulse Oximeter

### 3

**Description**
C- Reactive protein
**Timepoint**
28 days or until the marker is normalized
**Method of measurement**
Blood sample

### 4

**Description**
Procalcitonin
**Timepoint**
Until the marker is normalized
**Method of measurement**
Blood sample

### 5

**Description**
Lymphocyte count
**Timepoint**
Until the marker is normalized
**Method of measurement**
CBC

### 6

**Description**
Counting of CD3 +, CD4 + and CD8 + T cells
**Timepoint**
Before the first injection and after the third injection
**Method of measurement**
Flow cytometry

### 7

**Description**
CD4 + / CD8+ ratio
**Timepoint**
Before the first injection and after the third injection
**Method of measurement**
Flow cytometry

### 8

**Description**
Improve pneumonia evaluated by CT scan or Chest X-Ray
**Timepoint**
After the second and third infusions
**Method of measurement**
CT scan or plain Radiography

## Intervention groups

### 1

**Description**
Intervention group: In this group, umbilical cord Wharton’s jelly mesenchymal stem cells are infused at an initial dose of 0.5-1 million/kg. This process is performed three times. This intervention is done along with other standard treatments for this type of patients, varying in severity of COVID-19 Infectious, and in accordance with national and international guidelines.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: This group, like the intervention group, will receive all standard medication according to national and international guidelines, depending on the severity of COVID-19. But each time, placebo (normal saline) is infused.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Cell Gene Company
**Full name of responsible person**
Aliasghar Rezaei
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Avicenna Health Technology Incubation Center, NO. 60, Golestan 4th, Amirabadi St. ,Velenjak, Tehran, Iran.

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Dr@cellgenemedicine.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Cell Gene Medicine Company
**Full name of responsible person**
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info@cellgenemedicine.com
**Web page address**
https://cellgenemedicine.com/
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Cell Gene Medicine Company
**Proportion provided by this source**
100
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Persons

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Iranian academic center for education culture and research
**Full name of responsible person**
Aliasghar Rezaei
**Position**
Non-faculty physician
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Medical Biology
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## Person responsible for scientific inquiries

**Contact**
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**Full name of responsible person**
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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**
No - There is not a plan to make this available
**Statistical Analysis Plan**
Yes - There is 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**
Yes - There is 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
**Title and more details about the data/document**
Findings of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables.
**When the data will become available and for how long**
Available four months after the end of the study.
**To whom data/document is available**
Emergency medicine and infectious, pulmonology, intensive care, and other physicians.
**Under which criteria data/document could be used**
In the case of comparison with other similar trials or treatments.
**From where data/document is obtainable**
Avicenna Research Institute
**What processes are involved for a request to access data/document**
By referring to the central library and clinical trial center in Avicenna Research Institute can access the documents of participants, data, and results.
**Comments**