Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Human Placenta-Derived Mesenchymal Stem Cell Transplantation in Acute Respiratory Distress Syndrome (ARDS) Caused by COVID-19: Phase I Clinical Trial)

Protocol summary

Study aim

The safety evaluation of placenta-derived mesenchymal stem cell transplantation after in vitro culture in patients with COVID-19 related acute respiratory distress syndrome

Design

The study is a single arm, non randomized, non-blinded Phase 1 clinical trial in 10 patients with COVID-19-induced early ARDS

Settings and conduct

PLMSCs are manufactured according to GMP rules in a cleanroom facility. After passing QC tests, 1 million/kg of PLMSCs are packed in a bag and injected intravenously (during 15 minutes). The injections are done in university hospitals which located in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The confirmed positive result of RT-PCR test for SARS-COV2 acute infection Bilateral opacity of the lungs on CT scan PaO2 / FiO2 ratio <200 Exclusion Criteria: Presence of severe and irreversible disease with a life expectancy of fewer than 6 months Moderate to severe liver failure (Childs-Pugh score>12) History of chronic lung disease with PaCO2> 50 mmHg or history of oxygen consumption at home

Intervention groups

Patients with COVID-19-induced early ARDS will receive a single dose of approximately 1 million/kg human-derived placental mesenchymal stem cells intravenously in addition to routine treatments.

Main outcome variables

1. Acute complications of cell transplantation in the first 24 hours after transplantation and up to 28 days after treatment 2- Change in the severity of pneumonia during hospitalization up to 28 days after treatment 3- Changing the oxygen supply (PaO2 / FiO2) up to 28 days after treatment 4- Number of days of connection to the mechanical ventilation device and number of days of hospitalization in the ICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200621047859N4**
Registration date: **2021-01-03, 1399/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-03, 1399/10/14**
Update count: **0**

Registration date

2021-01-03, 1399/10/14

Registrant information

Name

Ramin Sarrami Forooshani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8879 6003

Email address

rsf1351@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-28, 1399/08/07

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Human Placenta-Derived Mesenchymal Stem Cell Transplantation in Acute Respiratory Distress Syndrome (ARDS) Caused by COVID-19: Phase I Clinical Trial)

Public title
The effects of mesenchymal stem cells in COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
COVID-19 infection confirmed with positive PCR test results with clinical signs including respiratory distress, cough, fever, decreased blood oxygen saturation, and imaging results in favor of ARDS Over 18 years of age Bilateral opacity of lungs on CT scan PaO2/FiO2 ratio < 200 Requires mechanical ventilation to increase oxygen saturation Written informed consent (according to the patient's condition, in case of unconscious consent, the consent will be obtained from the patient's guardian).

Exclusion criteria:
Less than 18 years of age More than 96 hours passed from the diagnosis of ARDS (Based on the Berlin definition of ARDS) Pregnancy or breastfeeding Presence of active malignancy which has been treated in the past two years Presence of severe and irreversible disease with a life expectancy of less than 6 months Moderate to severe liver failure (Childs-Pugh Score> 12) History of chronic lung disease with PaCO2>50 mm Hg or history of oxygen consumption at home Extensive trauma in the past 5 days History of lung transplantation Inability to provide informed consent or meet test conditions Class 3 or 4 pulmonary hypertension (WHO classification) History of pulmonary embolism or deep vein thrombosis (DVT) in the past three months

Age
From **18 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **20**

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
Research Ethics Committee of Motamed Cancer Institute Academic Center for Education Culture and Rese

Street address
No 146, South Ghandi, Vanaq Square, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1517964311

Approval date
2020-05-06, 1399/02/17

Ethics committee reference number
IR.ACECR.IBCRC.REC.1399.009

Health conditions studied

1

Description of health condition studied
Acute Respiratory Distress Syndrome

ICD-10 code
J80

ICD-10 code description
Acute respiratory distress syndrome

Primary outcomes

1

Description
Safety of PLMSCs intravenous injection

Timepoint
During hospitalization up to 28 days after treatment

Method of measurement
Physical examinations and blood tests

2

Description
Change the amount of oxygen supply

Timepoint
Up to 28 days after treatment

Method of measurement
Measurement of PaO2 / FiO2

3

Description
mortality

Timepoint

Up to 28 days after intervention

Method of measurement

The patients follow up

4

Description

Change in the severity of pneumonia

Timepoint

During hospitalization up to 28 days after treatment

Method of measurement

Physical examination - percentage of oxygen in the ventilator

Secondary outcomes

1

Description

Investigation of visceral insufficiency

Timepoint

Up to 28 days after transplantation

Method of measurement

Perform liver and kidney function tests on days 0, 7, 14 and 28

2

Description

C-reactive protein changes

Timepoint

Daily to +28

Method of measurement

Measurement of blood C-reactive protein

3

Description

Change in the number of lymphocytes

Timepoint

Day zero to week 12

Method of measurement

blood test

4

Description

Lung CT scan changes

Timepoint

Within 28 days after treatment

Method of measurement

Perform a CT scan of the lungs

5

Description

Duration of ICU admission

Timepoint

at the time of ICU discharge

Method of measurement

Number of admission days

Intervention groups

1

Description

Intervention group: Patients with resistant pneumonia caused by COVID-19 infection with acute symptoms of ARDS who have not responded to routine treatments. This group will receive about 10^6 cells/Kg Good manufacturing practices (GMP)-grade mesenchymal stem cells infusion over 10 minutes. The common treatments of patients will not be stopped.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr Samrand Fattah Ghazi

Street address

Imam Khomeini Hospital Complex, Dr Gharib Ave, Keshavarz Blvd, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Modiriat Atiye Bahman Company

Full name of responsible person

Sina Hasnalizadeh

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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
Modiriat Atiye Bahman Company
Proportion provided by this source
90
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
Academic

2

Sponsor
Name of organization / entity
Motamed Cancer Institute
Full name of responsible person
Dr Keivan Majidzadeh Ardebili
Street address
No.146, South Ghandi, Vanaq Square, Tehran, Iran
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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
Cell therapy budget of the Islamic Consultative Assembly
Proportion provided by this source
10
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Dr Ramin Sarrami Forooshani
Position
Associated Professor
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Virology
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Others

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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable