Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Placental Mesenchymal Stem cells for treatment of ARDS in Coronavirus infection, Phase 1 and 2 Clinical Trials

Protocol summary

Study aim
The main objective is to investigate the safety and efficacy of cell therapy in patients with ARDS caused by Coronavirus pneumonia as an open-labeled randomized clinical trial.

Design
A controlled randomized clinical trial phase 1-2

Settings and conduct
The study will be conducted at Masih Daneshvari Hospital and Shariati Hospital. Participants, outcome assessors, and analyzers are unaware of the allocation of study groups.

Participants/Inclusion and exclusion criteria
Patients aged 18 to 65 years are included in the study with a definitive diagnosis of COVID-19, which subsequently develops acute respiratory distress syndrome (mild or moderate). COVID-19 patients with severe underlying disease or allergies to the cell or its associated compounds are not included in the study.

Intervention groups
The patients allocated randomly to tree groups: 1) Intervention 1, Patients will receive three doses of MSCs. 2) Control, Patients will receive conventional therapy.

Main outcome variables
Safety ; Blood oxygen saturation; Decreased severity of pneumonia; Improvement of the acute respiratory syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200413047063N1**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-04, 1399/02/15**
Update count: **0**

Registration date
2020-05-04, 1399/02/15

Registrant information
Name
Masoud Soleimani
Name of organization / entity
Tarbiat Modares University
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2020-06-09, 1399/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Placental Mesenchymal Stem cells for treatment of ARDS in Coronavirus infection, Phase 1 and 2 Clinical Trials

Public title
Placental Mesenchymal Stem Cell Therapy for Acute Respiratory Distress Syndrome in Coronavirus Infection: A Phase 1-2 Clinical Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Confirmation of 2019-nCoV infection by RT-PCR Diagnosis of ARDS according to the Berlin definition of ARDS Requiring supplemental oxygen, PaO2/oxygen absorption concentration (FiO2) ≤ 300MMHG Pulmonary imaging shows that the focused progress > 50% in 24-48 hours Mild to Moderate 2019-nCoV pneumonia/ stay in the ICU <48 hours SOFA score between 2-3 point Pneumonia that is judged by chest radiograph or CT
Exclusion criteria:
Severe allergies or allergies after 1st injection to stem cell preparations and their components Patients with a malignant tumor, other serious systemic diseases, and psychosis Co-Infection of HIV, tuberculosis, influenza virus, adenovirus and other respiratory infection virus Patients with previous history of pulmonary embolism Liver or kidney SOFA score of more than 3 points; combined with other organ failure (need organ support), Stage 4 severe chronic kidney disease or requiring dialysis (i.e. estimated glomerular filtration rate (eGFR) < 30) Pulmonary obstructive pneumonia, severe pulmonary interstitial fibrosis, alveolar proteinosis, allergic alveolitis, and other known viral pneumonia or bacterial pneumonia Continuous use of immunosuppressive agents or organ transplants in the past 6 months In vitro life support (ECMO, ECCO2R, RRT) Pregnant or lactating women Uncontrolled underlying disease Be thought by researchers to be inappropriate to participate in this clinical study (Expected deaths within 48 hours, uncontrolled infections)

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomly divided into two equal groups using a randomized double AB blocking method based on a random number table.

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
Ethics committee of Tehran University of Medical Sciences

Street address
Keshavarz Blvd- Qods , TUMS

City
Tehran

Province
Tehran

Postal code
1417653911

Approval date
2020-03-19, 1398/12/29

Ethics committee reference number
IR.TUMS.VCR.REC.1399.009

Health conditions studied

1

Description of health condition studied
Acute Respiratory Distress Syndrome of COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
Adverse events assesment

Timepoint
At the same time of each intervention, 24 hours after each intervention, on days 6, 7, 14 and 28 after the first intervention

Method of measurement
Number of participants with treatment-related adverse events as assessed by CTCAE v4.0

2

Description
Blood oxygen saturation

Timepoint
At Baseline, simultaneously with each intervention and on days 5, 6, 7, 14 after the first intervention

Method of measurement
Evaluation of Pneumonia Improvement

Secondary outcomes

1

Description
Biomarkers concentrations in plasma

Timepoint
At baseline, 7, 14, 28 days after the first intervention

Method of measurement
Biochemical examination

2

Description
Respiratory efficacy
Timepoint
From baseline to day 7
Method of measurement
Evaluated by the increase in PaO2/FiO2 ratio

3

Description
Intensive care unit-free days
Timepoint
Up to day 8
Method of measurement
Number of day

4

Description
Change in clinical symptoms
Timepoint
At Baseline, simultaneously with each intervention and on days 5, 6, 7, 14 after the first intervention
Method of measurement
Evaluation of Pneumonia Improvement

Intervention groups

1

Description
Intervention group:Intervention group: The intervention group 1, Patients will receive three doses of MSCs. Two doses of 100×10e6 (±10%) cells will intravenously infuse as a normally dropped single dose over 10-12 minutes at the infusion speed of 4-5 mL/minute in day 0 and day 2 and day 4.
Category
Treatment - Other

2

Description
Control group:Patients will receive conventional therapy
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Mohammad Alian Nejad
Street address
Shariati Hospital., Jalal-e-Al-e-Ahmad Hwy
City
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Province
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Postal code
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Phone
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Email
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2

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Mohammad Reza Hashemian
Street address
Masih Daneshvari Hospital., Darabad Avenue., Shahid Bahonar Avenue
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Province
Tehran
Postal code
1956944413
Phone
+98 21 2610 5050
Email
smrhashemian@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Execution of Imam Khomeini's Order
Full name of responsible person
Mohammad Mokhber
Street address
Khaled Eslambuli Ave., 17 alley
City
Tehran
Province
Tehran
Postal code
1411533123
Phone
+98 21 8872 5923
Email
info@ setad.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Execution of Imam Khomeini's Order
Proportion provided by this source

40
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

2

Sponsor
Name of organization / entity
National Institute for Medical Research Development
Full name of responsible person
Reza Malekzadeh
Street address
No 21, Besat Street., Western Fatimid Street
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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
National Institute for Medical Research Development
Proportion provided by this source
20
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

3

Sponsor
Name of organization / entity
Oghaf Organization and charity
Full name of responsible person
Sayed Mahdi Khamooshi
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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
Oghaf Organization and charity
Proportion provided by this source
40
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

4

Sponsor
Name of organization / entity
Opal Parsian Company
Full name of responsible person
Mohamad Azimi
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No. 12, 29 Ave, Alvand st.,
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Phone
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Email
info@amencapital.co
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Opal Parsian Company
Proportion provided by this source
40
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
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Tarbiat Modares University

Full name of responsible person
Masoud Soleimani

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Hematology

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Person responsible for scientific inquiries

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Mohammad Vasei

Position
Professor

Latest degree
Subspecialist

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Pathology

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Person responsible for updating data

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soleim_m@modares.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
All collected deidentified IPD can be shared

When the data will become available and for how long
6 months after publication

To whom data/document is available
Researchers and clinicians

Under which criteria data/document could be used
Planning of similar studies in other academic centers

From where data/document is obtainable
e-Mail

What processes are involved for a request to access data/document
1-2 months after request

Comments