

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Mesenchymal Stem Cell Therapy for Acute Respiratory Distress Syndrome in Coronavirus Infection : A Phase 1 and 2 clinical trial

Protocol summary

Study aim

The main objective is to investigate the safety of cell therapy in patients with ARDS caused by Coronavirus pneumonia

Design

A Phase 1 and 2, non-controlled non-randomized clinical trial

Settings and conduct

The study will be conducted at Masih Daneshvari Hospital and Shariati Hospital.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 70 years are included in the study with a definitive diagnosis of COVID-19, which subsequently develops acute respiratory distress syndrome. 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 intervention group (n=11) will receive three doses of MSCs. Three doses of $200 \times 10^6 \pm (10\%)$ 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, day 2, day 4. The cells will inject in 50 ml saline containing 1% human serum albumin.

Main outcome variables

Side effects; oxygen saturation level; Improvement of clinical symptoms (fever, cough).

General information

Reason for update

The number of patients has increased. Correction of inclusion and exclusion criteria.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046526N1**

Registration date: **2020-04-13, 1399/01/25**

Registration timing: **retrospective**

Last update: **2020-06-10, 1399/03/21**

Update count: **2**

Registration date

2020-04-13, 1399/01/25

Registrant information

Name

Masoumeh Nouri

Name of organization / entity

Royan Stem Cell Technology Co

Country

Iran (Islamic Republic of)

Phone

+98 21 2763 5512

Email address

m.nouri@rsct.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-15, 1398/12/25

Expected recruitment end date

2020-03-25, 1399/01/06

Actual recruitment start date

2020-03-15, 1398/12/25

Actual recruitment end date

2020-03-25, 1399/01/06

Trial completion date

2020-04-25, 1399/02/06

Scientific title

Mesenchymal Stem Cell Therapy for Acute Respiratory Distress Syndrome in Coronavirus Infection : A Phase 1 and 2 clinical trial

Public title

Mesenchymal Stem Cell Therapy for Acute Respiratory Distress Syndrome in Coronavirus Infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Male or female 18-70 years old ARDS diagnosed SOFA score between 2-13 point Requiring mechanical ventilation and/or supplemental oxygen Pneumonia that is judged by chest radiograph or CT scan or confirmation of SARS-CoV-2 infection by qRT-PCR PaO₂/oxygen absorption concentration (FiO₂) ≤ 300 mmHG

Exclusion criteria:

Presenting severe allergies after 1st injection of stem cell Patients with a malignant tumor and psychosis Co-Infection of HIV, tuberculosis, adenovirus and another respiratory infection virus Patients with previous history of pulmonary embolism Moribund patient expecting death within 48 hours Continuous use of immunosuppressive agents or organ transplants in the past 6 months Pregnancy or breastfeeding

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **6**

Actual sample size reached: **11**

Randomization (investigator's opinion)

N/A

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

Ethic committee of National Institute for Medical Research Development

Street address

No 21, Besat Street., Western Fatimid Street

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۶۹۳۱۱۱

Approval date

2020-03-12, 1398/12/22

Ethics committee reference number

IR.NIMAD.REC.1398.412

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

Secondary outcomes

1

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

Intervention groups

1

Description

Intervention group: (n=6). Patients will receive three doses of MSCs. Three doses of 200×10⁶ (±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, day 2, day 4. The cells will inject in 50 ml saline containing 1% human serum albumin.

Category

Treatment - Other

Recruitment centers

1

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
City
تهران
Province
Tehran
Postal code
1956944413
Phone
+98 21 2610 5050
Email
smrhashemian@sbm.ac.ir

2

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Rasoul Alian Nejad
Street address
Shariati Hospital., Jalal-e-Al-e-Ahmad Hwy
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
Shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Abdol Hossein Shahverdi
Street address
No. 2, Hafez St., Banihashem St., Resalat Ave
City
تهران
Province
Tehran
Postal code
16635148
Phone
+98 21 2233 9940
Email
shahverdi@royaninstitute.org
Web page address
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iranian academic center for education culture and research
Proportion provided by this source
90
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

2

Sponsor
Name of organization / entity
National Institute for Medical Research Development
Full name of responsible person
Reza Mlekzadeh
Street address
No 21, Besat Street., Western Fatimid Street
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۶۹۳۱۱۱
Phone
+98 21 6693 8037
Email
dr.reza.malekzadeh@gmail.com
Web page address
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
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
Academic

Person responsible for general inquiries
Contact
Name of organization / entity
Royan Institute

Full name of responsible person

Morteza Zarrabi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Cell Therapy

Street address

No. 2, Hafez St., Banihashem St., Resalat Ave

City

Tehran

Province

Tehran

Postal code

16635148

Phone

+98 21 2233 9940

Email

m.zarrabi@rsct.ir

R&D Responsible

Latest degree

Ph.D.

Other areas of specialty/work

Cell Therapy

Street address

No. 24, East Hafez Alley., Bani Hashim Square., Bani Hashim St., Resalat Highway

City

Tehran

Province

Tehran

Postal code

۱۶۶۰۶۶۳۱۱

Phone

+98 21 2763 5512

Email

masoume.nouri2002@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Royan Institute

Full name of responsible person

Hossein Baharvand

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Stem Cell Biology

Street address

No. 2, Hafez St., Banihashem St., Resalat Ave

City

Tehran

Province

Tehran

Postal code

16635148

Phone

+98 21 2230 6485

Email

hossein.baharvand@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Royan Stem Cell Technology Co

Full name of responsible person

Masoume Nouri

Position**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

Email

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

1-2 months after request

Comments