Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 200×10e6± (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, 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

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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 200×10e6 (±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, 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

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2

Recruitment center

Name of recruitment center
Shariati hospital

Full name of responsible person
Rasoul Alian Nejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
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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

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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
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
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Other areas of specialty/work
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Person responsible for updating data

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masoume.nouri2002@gmail.com

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