

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Exosomes Derived from placental Mesenchymal Stem Cells as Treatment for Severe COVID-19: Phase 1 & 2 Clinical Trials

Protocol summary

Study aim

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

Design

Controlled randomized clinical trial phase 1-2

Settings and conduct

The study will be conducted at Nikan Hospital , Shariati Hospital, Esfahan Shahid Sadoughi Hospital, Yazd Shahid Sadoughi 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 Exosomes or its associated compounds are not included in the study.

Intervention groups

Patients allocated randomly to two groups: 1) Intervention 1, Patients will receive Six doses of Exosomes. 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: **IRCT20200413047063N2**

Registration date: **2021-04-14, 1400/01/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-08, 1400/04/17**

Update count: **1**

Registration date

2021-04-14, 1400/01/25

Registrant information

Name

Masoud Soleimani

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

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Email address

soleimani.masoud@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Exosomes Derived from placental Mesenchymal Stem Cells as Treatment for Severe COVID-19: Phase 1 & 2 Clinical Trials

Public title

Exosomes Derived from placental Mesenchymal Stem Cells as Treatment for Severe COVID-19: Phase 1 & 2 Clinical Trials

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 **70 years** old

Gender
 Both

Phase
 1-2

Groups that have been masked
No information

Sample size
 Target sample size: **50**

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

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Postal code

1417653911

Approval date

2020-09-19, 1399/06/29

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.454

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, 12 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

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 Six doses of Exosomes. One doses of 10×10¹⁰ (±10%) Exosomes 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 1 and day 2. group:

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 Aliannaejad

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Jalal al Ahmad st.

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2**Recruitment center****Name of recruitment center**

WestNikan Hospital

Full name of responsible person

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info@westnikanhospital.com

3**Recruitment center****Name of recruitment center**

Esfahan Shahid sadoughi Hospital

Full name of responsible person

Mojtaba Javani; Hossein Shafee

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Bozorgmehr st.,

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4**Recruitment center****Name of recruitment center**

Yazd Shahid Sadoughi Hospital

Full name of responsible person

Mohammad Samet

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Omid Cell and Tissue center

Full name of responsible person

Masoud Soleimani

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No.131, Shokrollah St, Kargar St

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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

Omid Cell and Tissue center

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

Persons

Person responsible for general inquiries

Contact
Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Vasei

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

Contact
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Other areas of specialty/work

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not 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