

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Cell therapy in patients with COVID-19 using mesenchymal stem cells: Phase 2 clinical trial

Protocol summary

Study aim

Evaluation of safety and efficacy of mesenchymal stem cells in patients with COVID19

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 20 patients. Software was used for randomization.

Settings and conduct

Stem cell injection to patients with acute pulmonary insufficiency with COVID19 (these cells are approximately 2×10^6 cells per kilogram (based on IBW) will be injected IV through the patient 3 times at 3-day intervals (0, 3, 6).) Shariati Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Age more than 18 years and less than 65 years 2- Clinical symptoms, including: $30 \leq PR$, $SO_2 \leq 93\%$ at rest or persistent hypoxia 3- Respiratory failure requires a ventilator 4- Chest x-ray: in Chest have multilobar infiltrates% <50 Exclusion criteria 1. Patient dissatisfaction 2. Pregnant patient 3. Age under 18 years and over 65 years 4. Patient with known active malignancy 5. Septic shock 6. Organ failure 7. Enter another study

Intervention groups

Treatment Group: Patients with coronavirus 19 who are transplanted with mesenchymal stem cells at a rate of two million per kilogram of body weight (based on IBW) through peripheral blood on days 0, 3, and 6. Control group: Participants receive routine treatment and placebo (based on IBW) intravenously on days 0, 3, and 6.

Main outcome variables

Clinical response; O2 saturation; inflammation cytokines. II-6 & II-10

General information

Reason for update

Request to change the phone number in the Registrant

information section to 989127249532

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044241N3**

Registration date: **2020-12-31, 1399/10/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-02, 1399/10/13**

Update count: **1**

Registration date

2020-12-31, 1399/10/11

Registrant information

Name

Mahshid Saleh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7736 5353

Email address

mahshid_saleh@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cell therapy in patients with COVID-19 using mesenchymal stem cells: Phase 2 clinical trial

Public title

Cell therapy in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Persistent hypoxemia despite receiving less than 93%

Saturation oxygen Respiratory failure requires a

Ventilator Chest has multilobar infiltrates

Exclusion criteria:

Patient dissatisfaction Pregnant patient Age under 18

years and over 65 years Patient with known active

malignancy Shock Organ failure

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization was used for achieving equal sample sizes in each group. For example, in intervention (I)/control (C) comparison, the process involved recruiting participants in short blocks and ensuring that half of the participants within each block were allocated to the "I" group and the other half to the "C" group. Within each block, however, the order of patients was random. We considered size 4 blocks. If I/C is represented by I/C methods, there would be 6 different ways in which 4 patients can be split evenly between 2 methods.

Blinding (investigator's opinion)

Double blinded

Blinding description

There are the same cell bags for infusion during the study. Cleanroom staff, DSMB, and data statisticians just aware of their contents.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

کمیته ملی اخلاق در پژوهش‌های زیست پزشکی

Street address

تهران- شهرک قدس (غرب)- بین فلامک جنوبی و زرافشان، خیابان

سیمای ایران- ستاد مرکزی وزارت بهداشت، درمان و آموزش

طبیقة سیزدهم، A، پزشکی، بلوک

City

Tehran

Province

Tehran

Postal code

.....

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.823

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes**1****Description**

Clinical response

Timepoint

28 days-From the time of cell injection until the 28th day

Method of measurement

clinical observation by Infectious Diseases Specialist

2**Description**

O2 saturation

Timepoint

Since the injection of the cell; 0,3,6 days.

Method of measurement

ventilator

Secondary outcomes**1****Description**

inflammation cytokines. IL-6 & IL-10

Timepoint

On days 0,3,6,14 - from the time of cell injection

Method of measurement

Assay by the Elisa

2**Description**

CD4 and CD8 markers
Timepoint
On days 0,3,6,14 - from the time of cell injection
Method of measurement
Flow Cytometry

3

Description
Evaluation of lung function
Timepoint
On days 0,14 - from the time of cell injection
Method of measurement
CT scan of the lungs

Intervention groups

1

Description
Intervention group: Patients with coronavirus 19 who undergo mesenchymal stem cell transplantation at a rate of 2 million per kilogram body weight (based on IBW) through peripheral blood (IV) on days 0, 3, and 6.
Category
Treatment - Other

2

Description
Control group: Participants with COVID19 receiving routine and placebo treatment (based on IBW) intravenously on days 0, 3, and 6.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان شریعتی
Full name of responsible person
دکتر ندا علیجانی
Street address
Tehran Province, Tehran, District 6, Jalal Al Ahmad Highway
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
Barakat Pharmaceutical Group
Full name of responsible person
Dr. Akbar Borandegi
Street address
No. 11, 5th Alley, Bucharest Ave., Argentina Sq, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
....
Phone
+98 21 8848 0156
Email
info@bpharmed.com
Web page address
http://www.bpharmed.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Barakat Pharmaceutical Group
Proportion provided by this source
80
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
Other

2

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Mohammad Ali Sahraian
Street address
Deputy of Research and Technology, sixth floor, Central University Organization, corner of St. Quds, Keshavarz Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
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Email
vcr@tums.ac.ir
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source
Tehran University of Medical Sciences
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

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mahshid Saleh - Dr Iman seyhoun

Position
Ph.D. student- Ph.D

Latest degree
Ph.D.

Other areas of specialty/work
Applied cell sciences

Street address
No. 88, Italy St, Eastern side of Tehran University,
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Mahshid_saleh@ymail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Javad Verdi; Neda Alijani

Position
دانشیار

Latest degree
Specialist

Other areas of specialty/work
Cell Therapy

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Email
javadverdi2019@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mahshid Saleh

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Cell Therapy

Street address
Tehran Province, Tehran, Eastern side of Tehran
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Email
Mahshid_saleh@ymail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no additional data.

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