

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Cell therapy in patients with COVID-19 using mesenchymal stem cells

Protocol summary

Study aim

Determination of Safety and Feasibility of Cell Therapy Using Mesenchymal stem Cells in Improving Patients with COVID-19

Design

one group with 5 uncontrolled patients, Phase I clinical trial

Settings and conduct

Intravenous injection of mesenchymal stem cells in Shariati hospital in Tehran

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Continuous hypoxemia, Respiratory failure requiring a Ventilator, Chest has multilobar infiltrates, Shock, Organ failure; Exclusion criteria: Patient dissatisfaction, Pregnant patient, Age less than 17 years, Patient with known active malignancy

Intervention groups

Mesenchymal stem cells about 2×10^6 (based on IBW) MSC / Kg by intravenous injection three times in a patient

Main outcome variables

Evaluation of Survival rate patients after injection. Laboratory Tests: Tests, Cell blood count albumin, ESR, D-dimer, LDH, CRP and

General information

Reason for update

Changes in initial outcomes, age limit, number of patients, and number of injections

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044241N2**
Registration date: **2020-04-22, 1399/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-14, 1399/06/24**

Update count: **2**

Registration date

2020-04-22, 1399/02/03

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

2020-04-20, 1399/02/01

Expected recruitment end date

2020-10-21, 1399/07/30

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

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 Shock Organ failure

Exclusion criteria:

Patient dissatisfaction Pregnant patient Age less than 17 years Patient with known active malignancy

Age

From 17 years old to 65 years old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 5

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

Iran National committee for Ethics in Biomedical research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

.....

Approval date

2020-04-13, 1399/01/25

Ethics committee reference number

IR.TUMS.VCR.REC.1399.203

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

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

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

Method of measurement

ventilator

3

Description

inflammation cytokines. Il-6 & Il-10

Timepoint

0,3,6,14 days-Since the injection of the cell

Method of measurement

Assay by the Elisa

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with COVID-19 who are transplanted with mesenchymal stem cells that are injected 2x 10⁶ (based on IBW) Via (IV) intravenous injection.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Dr Neda Alijani

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?

Yes

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

+98 21 8163 3685

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

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,
Tehran, Tehran Province

City

Tehran

Province

Tehran

Postal code

55469-14177

Phone

+98 21 4305 2000

Email

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

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cell Therapy

Street address

No. 88, Italy St, Eastern side of Tehran University,
Tehran, Tehran Province

City

Tehran

Province

Tehran

Postal code

55469-14177

Phone

+98 21 4305 2000

Email

javadvardi2019@gmail.com

University, Italy St, No. 88

City

Tehran

Province

Tehran

Postal code

55469-14177

Phone

+98 21 4305 2000

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

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