Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the efficacy and safety of cord-derived mesenchymal stem cell transplantation in the treatment of COVID-19

Protocol summary

Study aim

The purpose of this study was to evaluate the efficacy of cord-derived mesenchymal stem cell transplantation in the treatment of coadministration with other conventional therapies. It aims to reduce mortality and improve the immune system of patients.

Design

This study was a parallel randomized controlled clinical trial study design. The sample size of the study is 10 corona virus patients that will be assigned to intervention and control groups using simple randomization method.

Settings and conduct

This study will be performed to reduce the mortality of patients with COVID-19 and normalize blood tests and chest CT scan at Rasoul Akram Hospital of Iran University of Medical Sciences. Approved and admitted patients in infectious and intensive care units will be followed up for up to 28 days for the intended outcome after receiving the intervention.

Participants/Inclusion and exclusion criteria

Patients with acute form of COVID-19 infection who are confirmed by RT-PCR and HRCT will be included. Any confirmed pregnancy, viral disease, acquired or inherited immune deficiency, and mental illness will be excluded.

Intervention groups

Patients in the intervention group will be injected with an initial dose of 0.5–1 milion / kg of MSC. This process will be performed on the first, third and sixth days. This intervention will be supplemented with other treatments. The control group will receive placebo (normal saline) instead of the intervention.

Main outcome variables

Death, Pneumonia severity index, Oxygen index, C reactive protein, Procalcitonin, Lymphocyte count, CD3 +, CD4 + and CD8 + T cells count, Improved pneumonia using CT scan.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140528017891N8**
Registration date: **2020-03-28, 1399/01/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-28, 1399/01/09**
Update count: **0**

Registration date

2020-03-28, 1399/01/09

Registrant information

Name

Nader Tavakoli

Name of organization / entity

Iran University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8891 5410

Email address

tavakoli.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-24, 1399/01/05

Expected recruitment end date

2020-04-13, 1399/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the efficacy and safety of cord-derived mesenchymal stem cell transplantation in the treatment of COVID-19

Public title
The effect of stem cell transplantation in the treatment of COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients in acute phase Laboratory confirmation of SARS-COV-2 infection Pneumonia confirmed by chest x-ray or tomography Respiratory rate> 30 times / minute Oxygen Saturation less than 93% Arterial oxygen partial pressure (Pao2) /oxygen inhalation(Fio2) less than 300 mmHg No history of tumor or malignant disease

Exclusion criteria:
Pregnant patient with a positive pregnancy test or during lactation or who is planning to become pregnant during the study The definitive history of acquired or inherited immune deficiency diseases The definitive psychotic illness A history of serious mental illness or a history of suicide The use of NG tube Creatinine greater than 1.7 or hepatic enzymes three times normal or white blood cell count lower than 3000 and hemoglobin less than 10 Co-infection of human immunodeficiency viruses, Hepatitis B, Hepatitis C and Human T-lymphotropic virus

Age
From **18 years** old to **95 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Randomized

Randomization description
We will use a randomization method to minimize the researchers' opinion to select participation in study groups to control bias. After selection, participants will be assigned to the groups using a simple randomization method for received intervention and placebo in each participant. The randomization process will be performed using Random Allocation software, and since this study consists of two groups, the allocation outputs of the participants will be identified by A and B so the assign of each patient in each group is unpredictable to other members of the research team. We will notify the team manager after selecting each patient and they will send out each patient's intervention type based on the software output, without the known of other team members. But only the clinical care will be aware of any patient's intervention in cases where the patient's condition is inappropriate.

Blinding (investigator's opinion)
Double blinded

Blinding description
After selecting each patient to the study, the patients will be selected based on the randomization output was taken from the randomization software and matching it with the patient number of the intervention in such a way that both the patients and outcome assessor will not determine the type of intervention the patients receive. Blinding in this study was double blind. To maintain the blindness of the injection shape, color of the placebo will be similar to the main intervention so that patients and physicians evaluating the final outcome will be blind of the participant's interventions to minimize the bias in outcome measurement..

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2020-03-16, 1398/12/26

Ethics committee reference number
IR.IUMS.REC.1398.1400

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
RA01.0

ICD-10 code description
Severe Acute Respiratory Syndrome coronavirus

Primary outcomes

1

Description
Death

Timepoint
Up to 28 days after starting the study
Method of measurement
Patient observation and evaluation of vital signs

Secondary outcomes

1

Description
Evaluation of Pneumonia Severity Index
Timepoint
Up to 28 days
Method of measurement
PSI

2

Description
Evaluation of oxygen supply index
Timepoint
Discharge from ICU
Method of measurement
Pulse Oximeter

3

Description
C- Reactive protein
Timepoint
28 days or until the marker is normalized
Method of measurement
Blood sample

4

Description
Procalcitonin
Timepoint
Until the marker is normalized
Method of measurement
Blood sample

5

Description
Lymphocyte count
Timepoint
Until the marker is normalized
Method of measurement
CBC

6

Description
Counting of CD3 +, CD4 + and CD8 + T cells
Timepoint
Before the first injection and after the third injection
Method of measurement
Flow cytometry

7

Description
+ CD4 + / CD8 ratio
Timepoint
Before the first injection and after the third injection
Method of measurement
Flow cytometry

8

Description
Improve pneumonia evaluated by CT scan
Timepoint
After the second and third infusions
Method of measurement
CT scan

Intervention groups

1

Description
Intervention group: In this group, mesenchymal stem cells will be injected at an initial dose of 0.5-1 milion/ kg. This process will be performed on the first, third and sixth days. This intervention will be done along with other treatments for this type of patients, varying in severity of COVID Infectious, and in accordance with national and international guidelines. Mesenchymal Stem Cell is GMP-approved by SinaCell
Category
Treatment - Drugs

2

Description
Control group:This group, like the intervention group, will receive all routine medication according to national and international guidelines, depending on the severity of COVID-19. But on the first, third and sixth day, placebo (normal saline) will be injected
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
Nader Tavakoli
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St
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Email

tavakoli.n@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

MOM research and innovation center

Full name of responsible person

Amirhossein Asgary

Street address

Kordestan highway - south shiraz st - 68th st - MOM research and innovation center

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Email

info@mom.ir

Web page address

Grant name

MOM research and innovation center

Grant code / Reference number

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

Yes

Title of funding source

MOM research and innovation center

Proportion provided by this source

100

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Nader Tavakoli

Position

Association

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Omid Moradimoghadam

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Intensive care

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham Jamshidi

Position

General Pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is 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
Findings of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables.
When the data will become available and for how long
Availability four months after the end of study
To whom data/document is available
Emergency medicine and infectious, pulmonology, intensive care, and other specialists
Under which criteria data/document could be used
In the case of comparison with other similar trials or treatmen
From where data/document is obtainable
Iran University of Medical Sciences
What processes are involved for a request to access data/document
By referring to the central library and clinical trial center in Iran University of Medical Sciences can access to the documents of participants, data and results
Comments