Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Clinical trial study of safety and efficacy assessment of human umbilical cord matrix mesenchymal stem cell infusion on the treatment of new coronavirus 2019 pneumonia in humans

Protocol summary

Study aim

The purpose of this study is to evaluate the safety, efficacy, and dose determination of human umbilical cord matrix-derived mesenchymal stem cell injection in the treatment of new COVID-19 pneumonia in humans. The main aim is to decrease mortality.

Design

This study is a parallel randomized controlled clinical trial study design. The sample size of the study is 60 COVID-19 patients that are assigned to intervention and control groups using a simple randomization method.

Settings and conduct

This study is performed to decrease the mortality and other complications of patients with COVID-19 and normalize blood Parameters and chest CT scan at the hospital. Included and admitted patients in infectious and intensive care units, are followed up for up to 28 days for the intended outcome after receiving the intervention.

Participants/Inclusion and exclusion criteria

Patients with an acute form of COVID-19 infection who are confirmed by RT-PCR and HRCT are included. Any confirmed pregnancy, ARDS with other reasons, active cancerous disease, hematological disorders, heart failure, viral disease, acquired or inherited immune deficiency, and mental illness are excluded.

Intervention groups

Patients in the intervention group are injected with an initial dose of 0.5 -1 million/ kg of MSC. This process is repeated 3- 4 times. This intervention is supplemented with other treatments. The control group is received standard viral treatment along with placebo (normal saline) instead of the intervention.

Main outcome variables

Death, FIO2, Interleukin profile, Pneumonia severity index, Oxygen Saturation index, Procalcitonin, C reactive protein, 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: **IRCT20211012052743N1**
Registration date: **2021-11-06, 1400/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-06, 1400/08/15**
Update count: **0**

Registration date

2021-11-06, 1400/08/15

Registrant information

Name

Aliasghar Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8819 2932

Email address

rezaei690@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial study of safety and efficacy assessment of human umbilical cord matrix mesenchymal stem cell infusion on the treatment of new coronavirus 2019 pneumonia in humans

Public title
Stem cell therapy for COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients in the acute phase with Laboratory confirmation of SARS-COV-2 infection with RT-PCR Pneumonia confirmed by chest x-ray or Computed tomography Scan Respiratory rate> 30 times/minute Oxygen Saturation less than 93% Arterial oxygen partial pressure (Pao2) /oxygen inhalation(Fio2) less than 300 mm Hg No history of tumor or malignant disease CRP greater than normal range

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. Any active or treated Cancerous diseases. Creatinine greater than 1.7 mg/dL Co-infection of human immunodeficiency viruses, Hepatitis B, Hepatitis C and Human T-lymphotropic virus Any cardiac hemodynamic disorder Positive PPD test Positive syphilis test Treatment with cytotoxic drugs one month prior study

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
We use a randomization method to minimize the researchers' opinions to select participation in study groups to control bias. After selection, participants are assigned to the groups using a simple randomization method for received intervention and placebo in each participant. The randomization process is performed using Random Allocation software, and since this study consists of two groups, the allocation outputs of the participants are identified by A and B so assign of each patient in each group is unpredictable to other members of the research team. We do not notify the team manager after selecting each patient and they send out each patient's intervention type based on the software output, without the knowledge of other team members. Only the clinical care is aware of any patient's intervention in cases where the patient's condition is inappropriate.

Blinding (investigator's opinion)
Triple blinded

Blinding description
After selecting each patient to the study, the patients are selected based on the randomization output is taken from the randomization software and matching it with the patient number of the intervention in such a way that each patient, investigator, outcome assessor, and data analyzer does not determine the type of intervention the patients receive. Blinding in this study is triple blind. To maintain the blindness of the study the injection shape and color of the placebo are similar to the main intervention so that patients, physicians, and staff who evaluating the outcomes are blind to 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 Committees of Avicenna Research Institute

Street address
Avicenna Research Institute, Shahid Beheshti University, Darakeh Street

City
Tehran

Province
Tehran

Postal code
1984737384

Approval date
2021-08-24, 1400/06/02

Ethics committee reference number
IR.ACECR.AVICENNA.REC.1400.018

Health conditions studied

1

Description of health condition studied
COVID-19 disease

ICD-10 code
U07.01

ICD-10 code description
COVID-19 disease

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
The PSI/PORT score

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 or Chest X-Ray
Timepoint
After the second and third infusions
Method of measurement
CT scan or plain Radiography

Intervention groups

1

Description
Intervention group: In this group, umbilical cord Wharton’s jelly mesenchymal stem cells are infused at an initial dose of 0.5-1 million/kg. This process is performed three times. This intervention is done along with other standard treatments for this type of patients, varying in severity of COVID-19 Infectious, and in accordance with national and international guidelines.
Category
Treatment - Drugs

2

Description
Control group: This group, like the intervention group, will receive all standard medication according to national and international guidelines, depending on the severity of COVID-19. But each time, placebo (normal saline) is infused.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Cell Gene Company
Full name of responsible person
Aliasghar Rezaei
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Sponsors / Funding sources

1

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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
Cell Gene Medicine Company
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Aliasghar Rezaei
Position
Non-faculty physician
Latest degree
Medical doctor
Other areas of specialty/work
Medical Biology
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Person responsible for updating data

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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
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
Available four months after the end of the study.
To whom data/document is available
Emergency medicine and infectious, pulmonology, intensive care, and other physicians.
Under which criteria data/document could be used
In the case of comparison with other similar trials or treatments.
From where data/document is obtainable
Avicenna Research Institute
What processes are involved for a request to access data/document
By referring to the central library and clinical trial center in Avicenna Research Institute can access the documents of participants, data, and results.
Comments