Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Safety and efficacy study of allogeneic human menstrual blood stem cells secretome to treat severe Covid-19 patients, clinical trial phase I&II

Protocol summary

Study aim

Evaluation of safety and efficacy of injection of menstrual blood-derived stem cells secretome in patients with Covid-19 severe pneumonia

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 1 and 2 on 30 patients. Web random rendering software will be used for randomization.

Settings and conduct

The study population is selected according to the inclusion and exclusion criteria and consent is obtained from all and then these people are divided into two groups of intervention and control groups using randomization. The culture medium of allogeneic menstrual blood stem cells is collected in a cleanroom of Ibn Sina Research Institute and evaluated for contamination and then injected intravenously into patients with severe pneumonia caused by Covid-19.

Participants/Inclusion and exclusion criteria

Age 40 to 65 years, confirmed pneumonia caused by Covid-19, a positive test (RT-PCR) for Covid-19, diagnosed with severe disease: shortness of breath and respiratory distress, Respiratory rate ≥ 30 times/min; % of blood oxygen saturation at rest ≤ 90%; PaO2/FiO2 ratio≤ 300mmHg; Pulmonary infiltration more than 50% within 24 to 48 hours

Intervention groups

Intervention group: treat with injection of the allogeneic supernatant of menstrual blood stem cells. Control group: in addition to receiving routine national treatments, undergo intravenous injection of normal saline.

Main outcome variables

Determination of side effects and efficacy of injection of menstrual blood-derived allogeneic stem cells secretome in patients with severe pneumonia caused by Covid-19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180619040147N6**
Registration date: **2021-04-01, 1400/01/12**
Registration timing: **prospective**

Last update: **2021-04-01, 1400/01/12**
Update count: **0**

Registration date

2021-04-01, 1400/01/12

Registrant information

Name

Maryam Darzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2020

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy study of allogeneic human menstrual blood stem cells secretome to treat severe Covid-19 patients, clinical trial phase I&II

Public title
menstrual blood stem cell therapy for covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 40-65 years Voluntarily participate in this clinical trial and sign off "informed consent form" Chest imaging confirm COVID-19 featured lesions in the lung The SARS-CoV-2 nucleic acid test was positive Diagnosed with severe pneumonia of COVID-19: respiratory distress, Respiratory rate (RR) ≥ 30 times/min; resting oxygen saturation of 90% or less; arterial pressure of oxygen/the fraction of inspired oxygen≤ 300 mmHg; pulmonary imaging of focus within 24-48 hours > 50% progression
Exclusion criteria:
History of drug reactions or allergies Pneumonia caused by bacteria, Mycoplasma, Chlamydia, Legionella, fungi, or other viruses Airway obstruction due to lung cancer or unknown factors Carcinoid syndrome History of epilepsy and long-term use of anticonvulsant drugs during the last 3 years History of long-term use of immunosuppressive drugs History of chronic respiratory illness that requires long-term oxygen therapy The patient is on blood or peritoneal dialysis Creatinine clearance <15 ml / min Moderate to severe liver disease (Child-Pugh score> 12) History of deep vein thrombosis (DVT) or pulmonary embolism over the past 3 years Being under ECMO or high-frequency oscillatory ventilation support Diagnostic of HIV, hepatitis B, and syphilis Pregnant or lactating women Lack of consciousness and inability to provide informed consent by the patient
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a simple computer-aid randomization method is used. In this method, a list of numbers from 1 to 30 is prepared, and each number is randomly assigned to group A or B by a computer. Depending on the time of hospitalization, these numbers are assigned to the patients, respectively, and based on the list of patients, they are assigned to intervention group A (routine treatment with cell therapy) and control group B (routine treatment with normal saline injection). So that in each group there are 15 patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind trial (participants and data and outcome assessors). Because the drug is in the form of a stem cell supernatant cultured in a phenol-free culture medium, this medium is similar in color and volume to a normal saline injection serum, and therefore at the time of injection, The patient will not notice any difference in the color or volume of the medicine. The data analyst will also not know which of the drug / placebo options each patient receives and is unaware of the nature of the codes assigned to patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Academic Center for Education, Culture and Research (ACECR)- Biomedical Research Ethics Committee
Street address
1270, Secretariat of the Ethics Committee of ACECR,Deputy Director of Research and Technology, Headquarters of ACECR, Opposite the main door of Tehran University, Enghelab Street, Tehran
City
Tehran
Province
Tehran
Postal code
1936773493
Approval date
2021-02-28, 1399/12/10
Ethics committee reference number
IR.ACECR.REC.1399.005

Health conditions studied

1

Description of health condition studied
severe covid-19 patients
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description

Evaluation of allergic reaction to infusion of secretome derived from menstrual blood-derived allogeneic stem cells in patients with severe pneumonia caused by Covid-19

Timepoint

Simultaneously with each intervention, 24 hours after each intervention, Day 7 after the first intervention

Method of measurement

Clinical evaluation of this adverse effect according to CTCAE Version4 form

2

Description

Increase in the number of CD4 + and CD8 + T cells

Timepoint

On days 0, 3, 5, 7, 10, 14, 21, 28 after the first intervention

Method of measurement

Laboratory evaluation

3

Description

Decrease in serum CRP levels

Timepoint

On days 0, 3, 5, 7, 10, 14, 21, 28 after the first intervention

Method of measurement

Laboratory evaluation

4

Description

Decrease in serum levels of lactate dehydrogenase

Timepoint

On days 0, 3, 5, 7, 10, 14, 21, 28 after the first intervention

Method of measurement

Laboratory evaluation

5

Description

Decrease in serum Ferritin levels

Timepoint

On days 0, 3, 5, 7, 10, 14, 21, 28 after the first intervention

Method of measurement

Laboratory evaluation

6

Description

Decrease in serum D-Dimer levels

Timepoint

On days 0, 3, 5, 7, 10, 14, 21, 28 after the first intervention

Method of measurement

Laboratory evaluation

7

Description

Increase in interleukin-10 levels

Timepoint

On days 0, 3, 5, 7, 10, 14, 21, 28 after the first intervention

Method of measurement

Laboratory evaluation

8

Description

Decrease in interleukin-10 levels

Timepoint

On days 0, 3, 5, 7, 10, 14, 21, 28 after the first intervention

Method of measurement

Laboratory evaluation

9

Description

Reduce the size of the lesion on CT scan of the lungs

Timepoint

On days 0, 5, 10, 28 after the first intervention

Method of measurement

CT Scan

10

Description

Evaluation of injection site reaction of secretome derived from menstrual blood-derived allogeneic stem cells in patients with severe pneumonia caused by Covid-19

Timepoint

Simultaneously with each intervention, 24 hours after each intervention, Day 7 after the first intervention

Method of measurement

Number of participants with this treatment-related adverse events according to CTCAE Version4 form

Secondary outcomes

1

Description

Improving respiratory efficiency

Timepoint

Before the intervention until the one month after the first intervention on a daily basis

Method of measurement

Measuring PaO2 / FiO2 ratio or percentage of blood oxygenation

2

Description

Increasing the number of patients weaning from mechanical ventilation

Timepoint

Daily for one month after the first injection

Method of measurement

Observation

3

Description
Reduce the number of days hospitalized in the ICU
Timepoint
Daily for one month after the first injection
Method of measurement
Observation

4

Description
Reducing the incidence of failure of various organs
Timepoint
Daily for one month after the first injection
Method of measurement
Observation

5

Description
Reduce mortality rate
Timepoint
Daily for one month after the first injection
Method of measurement
Counting people

Intervention groups

1

Description
Intervention group: patients are treated by intravenous injection of 5 times supernatant culture medium of allogeneic menstrual blood-derived stem cells. After isolation and culture in a cleanroom under the GMP of Sina Biomedical Engineering Company GMP and passing and quality control tests, stem cells are stored in the cell bank. After cell thawing and culture in a GMP-approved culture medium, this surface culture medium is collected and centrifuged to remove cells and cell debris, and after filtration, quality control tests are performed on the collected culture medium. The 5 ml cell secretion is then filled into sterile vials and packaged. Each vial dissolved in 100 ml of normal saline is injected through a peripheral vein over a period of 30-60 minutes.
Category
Treatment - Drugs

2

Description
Control group: in addition to receiving routine national treatments for this disease, undergo intravenous injection of 100 ml of normal saline 5 times in completely similar conditions to the intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Ali Dehghan Manshadi
Street address
Dr. Gharib Street, At the end of Keshavarz Blvd, Imam Khomeini Hospital Complex
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Web page address
http://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Mohammad-Reza Sadeghi
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Avicenna Research Institute, Shahid Beheshti University, Shahid Chamran Highway, Tehran, Iran
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Email
sadeghi@ari.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iranian academic center for education culture and research
Proportion provided by this source
100
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
Ali Dehghan Manshadi
Position
Associate Professor
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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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
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
No - There is not 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
Not applicable
Data Dictionary
Not applicable