Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of efficacy and safety of mesenchymal stem cell transplantation in patients with COVID-19 pneumonia

Protocol summary

Study aim
Evaluation of efficacy and safety of mesenchymal stem cell transplantation in patients with COVID-19 pneumonia
Design
Parallel double blind randomized clinical trial study
Settings and conduct
The umbilical cord will be provided by volunteer donors at Fatemieh Hospital. Patients with COVID 19 with acute respiratory distress who have been admitted to the intensive care unit of Sinai Hospital and have not responded to conventional therapies will be included to the study.
Participants/Inclusion and exclusion criteria
Patients with PCR positive test, with acute respiratory infectious symptoms and severe lung involvement, will be included to the study and pregnant women patients or patients with sepsis or cancer exclude from the study.
Intervention groups
Intervention group: Receiving mesenchymal stem cell + common treatment Control group: Receiving common treatment
Main outcome variables
Patient respiratory status, measurement of inflammatory cytokine levels and patient life status

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200426047206N2**
Registration date: **2020-07-06, 1399/04/16**
Registration timing: **prospective**

Last update: **2020-07-06, 1399/04/16**
Update count: **0**
Registration date
2020-07-06, 1399/04/16

Registrant information
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Salman Khazaei
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-22, 1399/05/01
Expected recruitment end date
2020-12-21, 1399/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of efficacy and safety of mesenchymal stem cell transplantation in patients with COVID-19 pneumonia

Public title
The efficacy and safety of mesenchymal stem cell transplantation in patients with COVID-19 pneumonia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Positive PCR test Age between 18-70 years patient with acute respiratory infectious symptoms and severe lung involvement
Exclusion criteria:
Sepsis Pregnancy Cancer

Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose, we will use the BalancedBlock Randomization method (block size=4). Random allocation software will be used for this purpose. At first, we prepare two sheets of paper. We write "Intervention" on a paper and "Standard treatment" on another. Mix the sheets together and place them on the desk drawer. With the referral of each of the eligible patients, one of the cards will be drawn randomly and based on this drawn card, it will be assigned to one of the two groups. It should be noted that the drawn sheets will not be returned to the drawer until all four sheets have been removed. After all four sheets are drawn randomly, all the sheets are returned to the drawer and the above operation will be continued for the next four patients until the desired sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
No information will be provided to clinical caregivers and evaluators about which group got the cell and which one has not taken a cell.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Fahmideh
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2020-06-27, 1399/04/07
Ethics committee reference number
IR.UMSHA.REC.1399.330

Health conditions studied

1

Description of health condition studied
COVID-19 disease
ICD-10 code
RA01.0
ICD-10 code description
Severe Acute Respiratory Syndrome coronavirus

Primary outcomes

1

Description
Patient respiratory status
Timepoint
روزانه به مدت دو هفته
Method of measurement
Using CT scan image, physical examination, oxygen saturation percentage

2

Description
Inflammatory factors
Timepoint
Before and two week after intervention
Method of measurement
Elisa

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group receiving mesenchymal stem cells. In this group, patients are received 1 million Umbilical core-derived MSCc/BW by intravenous injection (provided by volunteer donors at Fatemieh Hospital) (Through the catheter and the Central vein and from the superior vena cava vein). Also, in addition to cell therapy, Other routine treatments (The last national protocol for COVID-19 treatment) will be given to patients according to the physician's supervision.The umbilical cord will be provided by volunteer donors at Fatemieh Hospital and after that will be cultured and expanded in the cleanroom of Hamadan University of Medical Sciences.
Category
Treatment - Other

2

Description
Control group: Receiving routine therapies (The last national protocol for COVID-19 treatment) (without stem cell)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Sara Soleimani Asl
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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
Hamedan University of Medical Sciences
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
Hamedan University of Medical Sciences
Full name of responsible person
Salman Khazaei
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Assistance professor
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Person responsible for updating data

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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
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