

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Feb 2023

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 Fatemeh 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

Name

Salman Khazaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0548

Email address

salman.khazaei61@gmail.com

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 Fatemeh 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 Fatemeh 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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Mirzadeh Eshghi Street

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6516848741

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s_khazaeii@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact

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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