

# 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 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

**Street address**

Mirzadeh Eshghi Street

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6516848741

**Phone**

+98 81 3827 4184

**Email**

s\_khazaeii@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Sara Soleimani asl

**Street address**

Fahmideh

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**Province**

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**Phone**

+98 81 3838 0496

**Email**

sr\_soleimani@yahoo.com

**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**

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## Person responsible for updating data

### Contact

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**Fax**

### Email

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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