

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

Investigation the adipose and placenta-derived mesenchymal stem cells effect on the respiratory distress syndrome in patients with COVID-19: a pilot study

Protocol summary

Study aim

Evaluation of the adipose and placenta-derived mesenchymal stem cells effect on the respiratory distress syndrome in patients with COVID-19 (a pilot study)

Design

Clinical trials have two groups, the first group receiving three stem cells with common treatment and the control group receiving only the most common treatment, with parallel groups, single blind, phase one on six patients.

Settings and conduct

The place of study is infectious diseases department of Imam Reza Hospital in Kermanshah. Blinding process: the study will be double-blind in which participants and analyzer will be kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: COVID-19 patient; acute respiratory infectious and distress symptoms; Inclusion criterion: COVID-19 patient with mild respiratory infection and mild lung involvement

Intervention groups

Intervention group: patients are treated with Mesenchymal cells in addition to common treatment protocol. Control group: they just receive the common treatment.

Main outcome variables

Biomarker on cells; respiratory symptoms and lung function in patients; Il-6 and Il-1 in patient blood

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200418047121N2**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **prospective**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

KAMRAN MANSOURI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6473

Email address

kmansouri@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the adipose and placenta-derived mesenchymal stem cells effect on the respiratory distress syndrome in patients with COVID-19: a pilot study

Public title

Stem cell therapy in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with COVID19 Acute respiratory infectious symptoms and severe lung involvement

Exclusion criteria:

Patients with mild symptoms and mild lung involvement

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **6**

More than 1 sample in each individual

Number of samples in each individual: **1**

6 Patients with COVID19 are selected with acute respiratory infectious symptoms and severe lung involvement (at the discretion of the medical team)

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

No information will be given to clinical evaluators and participants as to which group received the cells and which group did not

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Medical Biology Research Center; Parstar blvd; Roodaki

City

Kermanshah

Province

Kermanshah

Postal code

67417

Approval date

2020-04-14, 1399/01/26

Ethics committee reference number

IR.KUMS.REC.1399.065

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

biomarker expression

Timepoint

two weeks after last cell therapy

Method of measurement

Flowcytometry

2

Description

IL-6 and IL-1 Level

Timepoint

Before Cell injection and two weeks after cell injection

Method of measurement

Elisa Kit

3

Description

Respiratory and lung function

Timepoint

Before Cell injection and two weeks after cell injection

Method of measurement

Physical examination , O2 saturation and CT Scan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Three Patients suffering from COVID-19 with acute respiratory infections and severe lung involvement will be allocated to this group under the supervision of the medical staff. Those patients with severe symptoms (pneumonia and ARDS) will be suggested to join this pilot study and after obtaining the written informed consent, they participate in this investigation at Emam Reza hospital (at transplantation

ward). Afterward, 1×10^6 cells/Kg of weight are prepared for transplantation in addition to common treatment protocol. Cell transplantation is repeated once every 3-4 days during a 14-day period (totally three doses). After cell transplantation, patients are assessed for two weeks, all the symptoms and side effects such as allergic reactions and secondary infections also the level of the cytokines variation, the level of CRP and the oxygen saturation, lymphocyte count, the chest CT and the respiratory rate will be assessed and compared with control group.

Category

Treatment - Drugs

2**Description**

Control group: just receive the common treatment. Patients are assessed for two weeks, all the clinical symptoms such as the level of the cytokines, the level of CRP and the oxygen saturation, lymphocyte count, the chest CT and the respiratory rate are examined.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bostan hospital

Full name of responsible person

Kamran Mansouri

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

No. 2 Central Building, Kermanshah University of
Medical Sciences, Shahid Beheshti boulevard

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Web page address

<https://vc-research.kums.ac.ir/en/home>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Charity Association of Kermanshah University of Medical
Sciences

Proportion provided by this source

30

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**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Kamran Mansouri

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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