Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Investigation of the effects of the exosomes derived from placental mesenchymal stem cells on the oxygen saturation and biological markers of patients with COVID-19

Protocol summary

Study aim

Investigation of the effects of the exosomes derived from placental mesenchymal stem cells on the oxygen saturation and biological markers of patients with Coronavirus

Design

This study is a randomized double-blinded clinical trial with a control group. In this double-blinded study, Patients are aware of participating in the study and receiving the new drug, but the researcher and the participant will be kept blinded to which group will receive the new drug and which group will receive the placebo. In this randomized study, phase 2/3 will be conducted on at least 8 patients with Covid-19. A random number table is used for randomization and participants are assigned to intervention and control groups.

Settings and conduct

This study that will be conducted in Imam Reza hospital of Kermanshah is double-blinded. The researcher and the participants, contributors have no role in the process of randomization and assignment of intervention and control groups. First, mesenchymal stem cells are isolated from the placenta by enzymatic digestion. Then, the presence of special surface markers is studied by flow cytometry, and their ability to differentiate into mesoderm categories such as bone, fat, and cartilage is examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infected patients with Coronavirus; Diagnosis of acute respiratory syndrome according to Berlin criteria; Requires oxygenation or confirmed pneumonia Exclusion criteria: Liver or kidney SOFA score more than 3

Intervention groups

The intervention group in addition to the usual treatment protocol will receive single-dose exosomes (one billion exosomes per kilogram)by injection twice on two consecutive days. The control group will receive the usual medicine in addition to the placebo (50cc dextrose saline).

Main outcome variables

Oxygen saturation; Neutrophil lymphocyte ratio; Ferritin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N164**
Registration date: **2021-04-01, 1400/01/12**
Registration timing: **retrospective**

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

Registration date

2021-04-01, 1400/01/12

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effects of the exosomes derived from placental mesenchymal stem cells on the oxygen saturation and biological markers of patients with COVID-19

Public title

Investigation of the effects of the exosomes on patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infected patients with Corona virus based on CRISPR test (PCR) Diagnosis of acute respiratory syndrome according to Berlin criteria Requires oxygenation or confirmed pneumonia by radiologically or CT Oxygen uptake concentration Progression of of pulmonary edema more than 50% within 24-48 hours Mild to moderate pneumonia caused by a new coronavirus

Exclusion criteria:

Serious underlying illness or psychosis Co-infection with HIV, tuberculosis, influenza virus, adenovirus and other viral respiratory infections Liver or kidney SOFA score more than 3

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **8**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random number table, patients are divided into two groups of at least 4. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7 will be assigned to the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blinded study, the researcher and the patient are unaware of who is receiving the new drug. Initially, a code is considered by the nurse for the intervention group and the placebo group. The code of the intervention group is A and the code of the placebo group is B.The new drug and placebo are injected into the serum, which is the same shape and size for both groups.

Placebo

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

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti,

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-11-10, 1399/08/20

Ethics committee reference number

IR.kums.rec.1399.807

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Oxygen saturation

Timepoint

2 to 3 days after injection,daily for two weeks

Method of measurement

Using a pulse oximeter

2

Description
Neutrophil to lymphocyte ratio
Timepoint
2 to 3 days after injection,daily for two weeks
Method of measurement
Using a blood test (To determine the percentage of neutrophils and lymphocytes, the optical method or light microscope and Giemsa staining is used)

3

Description
Ferritin
Timepoint
2 to 3 days after injection,daily for two weeks
Method of measurement
Using a blood test and Chemiluminescence immunoassay method

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group in addition to the usual treatment will receive single-dose exosomes (one billion exosomes per kilogram) twice on two consecutive days by injection. Regarding the pharmaceutical company, it has not a pharmaceutical company, separation and processing are done in the cell culture laboratory of the Biological Research Center of Kermanshah University of Medical Sciences.
Category
Treatment - Drugs

2

Description
The control group, in addition to the placebo(50cc dextrose saline), will receive the usual medicine (Recigen; 12000000 unit every other day till 5 dosages, Kaletra, sevodak: daily for 5 days, high dose dexamethasone for 7 days with tapering).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Dr. Kamran Mansouri
Street address
Emam Reza Hospital, Parastar Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti,
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fnajafi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Kamran Mansouri
Position
Faculty member of Kermanshah University of Medical

Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Molecular Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr. Faizullah Mansouri

Position
Faculty member of Kermanshah University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Faculty member of Kermanshah University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Molecular Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is 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
Not applicable

Title and more details about the data/document
The main outcomes of the study will be shared.

When the data will become available and for how long
6 months

To whom data/document is available
If requested, results will be made available to other academic researchers

Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable
Send E-mail to the responsible for the update to get the documentation

What processes are involved for a request to access data/document
Documentation will be emailed within a 15-day timeframe

Comments