

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

Phone

+98 83 1821 4653

Email address

froughi@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

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

kamranmansouri@gmail.com

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,

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

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
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
kamranmansouri@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
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
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
fmansoury@yahoo.com

Person responsible for updating data

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
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
kamranmansouri@gmail.com

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