Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the therapeutic effect of nebulized addipose tissue- derived mesenchymal stem cells conditioned media on covid -19 pneumonia

Protocol summary

Study aim
Evaluation of the therapeutic effect of nebulized addipose tissue- derived mesenchymal stem cells conditioned media on covid -19 pneumonia

Design
Includes 15 patients who will receive the optimal culture medium by inhalation for 8 days in two doses at 8:30 in the morning and 4 in the afternoon. This study will be performed in phase 0. The control group includes patients whose symptoms were recorded on the first day of admission and will be compared with the results of their recovery on the day of discharge.

Settings and conduct
The present study will be performed at Kerman University of Medical Sciences, Afzalipour Hospital. Thus, after isolation and expansion of mesenchymal stem cells, their optimal conditioned media was isolated and after reaching the appropriate concentration will be nebulized by nebulizer in 15 patients hospitalized with Covid 19 for 5 days and in Used twice a day. One and three days after receiving the last dose of treatment, people's recovery will be evaluated.

Participants/Inclusion and exclusion criteria
Patients with Covid 19 who have been infected for a week and who have been hospitalized for 48 hours despite receiving medication and oxygen have not improved their condition and their arterial blood oxygen saturation percentage is below 88%.، Patients with arterial blood oxygen saturation above 88%.

Intervention groups
experimental group: Includes 15 patients who will receive the optimal culture medium by inhalation for 8 days in two doses at 8:30 in the morning and 4 in the afternoon. control group: The control group includes patients whose symptoms were recorded on the first day of admission and will be compared with the results of their recovery on the day of discharge.

Main outcome variables
CRP, Lung fibrosis, number of WBC, fever, LDH

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210919052520N1**
Registration date: **2022-01-13, 1400/10/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-13, 1400/10/23**
Update count: **0**

Registration date
2022-01-13, 1400/10/23

Registrant information

Name
Mona Saheli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3331 6308

Email address
m.saheli@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-05-20, 1401/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the therapeutic effect of nebulized addipose tissue- derived mesenchymal stem cells conditioned media on covid -19 pneumonia

Public title
Inhalation of stem cell products in patients with covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Covid 19 who have been infected for a week and who have been hospitalized for 48 hours despite receiving medication and oxygen have not improved their condition and their arterial blood oxygen saturation percentage is below 88%.
Exclusion criteria:
Patients with arterial blood oxygen saturation above 88%.
Age
To **60 years** old
Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of kerman university of medical sciences
Street address
haft-bagh alavi airway
City
Kerman
Province
Kerman
Postal code
76169-14115
Approval date
2021-12-22, 1400/10/01
Ethics committee reference number
IR.KMU.REC.1400.546

Health conditions studied

1

Description of health condition studied
covid-19
ICD-10 code
ICD-10 code description
https://www.who.int/publications/m/item/covid-19-update-for-icd-10

Primary outcomes

1

Description
Treatment of patients suffer from Covid 19 nebulization of conditioned-medium derived from human adipose tissue mesenchymal stem cell
Timepoint
Comparison of the improvement of patients with covid-19 disease before the intervention and after 5 days of therapeutic intervention
Method of measurement
blood laboratory test , CT-Scan

Secondary outcomes

1

Description
Reduction of lung damage
Timepoint
Measurement of lung damage before and after therapeutic intervention
Method of measurement
CT-Scan

2

Description
CRP, LDH, WBC measurement
Timepoint
Before and after therapeutic intervention
Method of measurement
blood laboratory test

3

Description
fever
Timepoint
Before and after therapeutic intervention
Method of measurement
Thermometer

Intervention groups

1

Description
Intervention group: Includes 15 patients who will receive the conditioned-medium by nebulization for 8 days in two doses at 8:30 in the morning and 4 in the afternoon.
Category
Treatment - Drugs

2

Description
Control group: The control group includes patients whose symptoms were recorded on the first day of admission and will be compared with the results of their recovery on the day of discharge.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour hospital
Full name of responsible person
Mona Saheli, Meisam Yousefi
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
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2

Recruitment center
Name of recruitment center
Afzalipour hospital
Full name of responsible person
Mona Saheli, Meisam Yousefi
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Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mona Saheli
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Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
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kerman
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7616913555
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Email
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Mona Saheli
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Histology
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data of our study include information on the status and biochemical characteristics of patients after treatment.

When the data will become available and for how long
one year after

To whom data/document is available
general publication

Under which criteria data/document could be used
To treat patients if treatment is successful and publicly disseminate data

From where data/document is obtainable
principle investigator

What processes are involved for a request to access data/document
The applicant submits the request via email to the executor and receives a response.

Comments