

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 2026

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

Protocol summary

Study aim

Evaluation of the therapeutic effect of nebulized adipose 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 adipose 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

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Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

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Person responsible for scientific inquiries

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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