

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

**Street address**

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

**City**

Kerman

**Province**

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**Postal code**

7616913355

**Phone**

+98 34 3132 8000

**Fax**

+98 34 3132 8000

**Email**

saheli.mona@gmail.com

**Web page address**

<https://ah.kmu.ac.ir/fa>

### 2

#### Recruitment center

**Name of recruitment center**

Afzalipour hospital

**Full name of responsible person**

Mona Saheli, Meisam Yousefi

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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

**Street address**

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

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kerman

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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

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
assistant professor  
**Latest degree**  
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**Other areas of specialty/work**  
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**Email**  
saheli.mona@gmail.com

## Person responsible for updating data

### 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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**Postal code**  
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**Email**  
saheli.mona@gmail.com

## 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