Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study the effect of intravenous injection of dental pulp mesenchymal stem cells in treatment of patients with COVID-19 pneumonia- A Phase 2&3 Clinical Trial

Protocol summary

Study aim

Investigation the effect of intravenous injection of dental pulp mesenchymal stem cells in treatment of patients with COVID-19 pneumonia- A Phase 2&3 Clinical Trial

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 3 and 2 on 120 patients. A simple randomization method is used for randomization.

Settings and conduct

This study is performed in the field of infectious diseases. It is located in Afzalipour Hospital and the Comprehensive Center for Stem Cells and Regenerative Medicine of Kerman University of Medical Sciences. In this study, 2 groups are intervened. Both groups receive conventional therapies. In addition, in the first group, patients have oxygen masks and receive stem cells, and in the second group, patients receive intubation and receive mesenchymal stem cells.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged between 18-95 years Patients Approved for Covirus 19 by Laboratory Methods Patients with mild to moderate respiratory distress Hospitalization in the ICU Exclusion criteria: Patients undergoing other clinical trials Patients with underlying diseases including diabetes, heart disease, respiratory disease, cancer patients and patients undergoing chemotherapy

Intervention groups

Two groups of patients are involved in this study. The first group uses an oxygen mask. The second group is patients admitted to the ICU who are intubated. Both groups receive mesenchymal stem cells in addition to conventional therapies. In addition to these two intervention groups, there are two control groups, the first group receiving only oxygen masks and conventional therapies, and the second group of patients admitted to the ICU receiving only conventional therapies.

Main outcome variables

Pulmonary condition, RNA expression of COVID19 virus, Lymphocytes count, Study of clinical signs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140911019125N8**
Registration date: **2020-09-26, 1399/07/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-26, 1399/07/05**
Update count: **0**

Registration date

2020-09-26, 1399/07/05

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32 24618

Email address

afarsinejad@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-10, 1399/06/20

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of intravenous injection of dental pulp mesenchymal stem cells in treatment of patients with COVID-19 pneumonia- A Phase 2&3 Clinical Trial

Public title

The effect of dental pulp mesenchymal stem cells in treatment of corona disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged between 18-95 years Patients Approved for Covirus 19 by Laboratory Methods Patients with mild to moderate respiratory distress Hospitalization in the ICU

Exclusion criteria:

Patients undergoing other clinical trials Patients with underlying diseases including diabetes, heart disease, respiratory disease, cancer patients and patients undergoing chemotherapy.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method is used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

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

Kerman university of medical science, Haft Bagh Blvd, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616911333

Approval date

2020-09-16, 1399/06/26

Ethics committee reference number

IR.KMU.REC.1399.373

Health conditions studied

1

Description of health condition studied

Corona virus disease

ICD-10 code

U07.1

ICD-10 code description

COVID19, virus identified

Primary outcomes

1

Description

Pulmonary Condition

Timepoint

At the beginning of the study and 1 day and 2 days, 4 days, 7 days and 14 days after the start of the study

Method of measurement

CT scan

2

Description

Expression of nucleic acid of virus

Timepoint

At the beginning of the study and 1 day and 2 days, 4 days, 7 days and 14 days after the start of the study

Method of measurement

real time PCR

3

Description

Lymphocytes count

Timepoint

At the beginning of the study and 1 day and 2 days, 4 days, 7 days and 14 days after the start of the study

Method of measurement

Flowcytometry

4

Description

Patients clinical signs

Timepoint

At the beginning of the study and 1 day and 2 days, 4 days, 7 days and 14 days after the start of the study

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The extracted tooth is brought to the laboratory. After separating the tooth pulp, it is digested enzymatically and cultured. Once the cells have reached a sufficient level, 40 million cells are injected intravenously into the patient at a time. These patients are patients admitted to the ICU who use an oxygen mask and receive stem cells upon arrival at the ICU in addition to routine treatments.

Category

Treatment - Other

2

Description

Intervention group: The extracted tooth is brought to the laboratory. After separating the tooth pulp, it is digested enzymatically and cultured. Once the cells have reached a sufficient level, 40 million cells are injected intravenously into the patient at a time. These patients are hospitalized in an ICU that is intubated and, in addition to the usual treatments, receive stem cells at the time of connection to the device.

Category

Treatment - Other

3

Description

Control group: ICU patients who wear oxygen masks receive only routine treatment and are monitored from the time they enter the ICU.

Category

N/A

4

Description

Control group: Patients admitted to the ICU who are intubated and receive only routine treatments are monitored upon connection to the device.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Mehrdad Farrokhnia

Street address

Imam Khomeini Highway, Afzali pour Hospital, Kerman, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Alireza Farsinejad
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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afarsinejad@kmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no additional data.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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
In our study non of the personal data of patients will be shared. Only data that are related to outcomes of intervention will be shared
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
The data will be available for people working in academic institutions and clinicians.
Under which criteria data/document could be used
Applicants are only allowed to use received data in clinical and they are not allowed to published them
From where data/document is obtainable
1- Phone: 034-31325374 2- e-mail: afarsinejad@kmu.ac.ir 3- Fax: 034-31325375 4- address: Haft bagh Blvd, Kerman university of medical science Dr. Alireza Farsinejad
What processes are involved for a request to access data/document
Applicant can receive information after contact and send e-mail up to 10 days.
Comments