Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evolution of Allogenic Mesenchymal stem cell- derived Umbilical cord transplantation for ARDS patients infected with COVID19.

Protocol summary

Study aim
Evolution of Allogenic Mesenchymal stem cell- derived Umbilical cord transplantation for ARDS patients infected with COVID19

Design
Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct
Randomise intervention, Ghaem Hospital, Mashhad

Participants/Inclusion and exclusion criteria
Covid-19 patient with acute respiratory infectious symptoms and severe lung involvement (Inclusion criteria) Covid-19 patient with mild respiratory infectious symptoms and mild lung involvement (Exclusion criteria)

Intervention groups
Intervention group: Receiving MSCc along with common treatment Control group : Receiving common treatment

Main outcome variables
Respiratory status and pulmonary disease in patients,Measurement of inflammatory cytokine levels,Cell population and markers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160809029275N1**
Registration date: **2020-05-30, 1399/03/10**
Registration timing: **prospective**

Last update: **2020-05-30, 1399/03/10**
Update count: **0**

Registration date
2020-05-30, 1399/03/10

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51376276015

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tavakolaj@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-14, 1399/03/25

Expected recruitment end date
2020-10-16, 1399/07/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evolution of Allogenic Mesenchymal stem cell- derived Umbilical cord transplantation for ARDS patients infected with COVID19.

Public title
stem cell therapy in Covid-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Covid-19 patient with acute respirstory infectious symptoms and severe lung involvement Pulmonary compliance more than 40 Age category 18-70 years PI02/FIo2 between 100 - 300

Exclusion criteria:
Covid-19 patient with Sepsis Pregnancy The presence of

malignancy or other underlying diseases Patient with age conditions outside the range of 18-70 years

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

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization. Eligible patients randomly and without considering a specific factor are divided into two groups: intervention and control.In this method, the random number table is used .So that people with individual codes are allocated in a group and people with couple codes are allocated in the other group.This method of randomization is performed to remove bias.

Blinding (investigator's opinion)
Double blinded

Blinding description
No information will be provided to clinical caregivers and evaluators about which group got the cell and which one has not taken a cell.This method of blinding is performed to remove bias.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Regional Ethics Committee of Mashhad University of Medical Sciences

Street address
Daneshgah Ave, Qoreishi Building,Vice chancellor for research and technology

City
Mashhad

Province
Razavi Khorasan

Postal code
913881394

Approval date
2020-04-23, 1399/02/04

Ethics committee reference number
IR.MUMS.REC.1399.150

Health conditions studied

1

Description of health condition studied
Covid-19 disease

ICD-10 code
RA01.0

ICD-10 code description
Severe Acute Respiratory Syndrome coronavirus

Primary outcomes

1

Description
Respiratory symptoms and pulmonary function in patients

Timepoint
In onset of study and days 2, 7 and 14 after the second injection

Method of measurement
Using CT scan image , physical examination , Oxygen saturation Percentage

2

Description
Evaluation of IFN-γ,IL4,TGF-β,IL1-β , IL-6 and TNF-a cytokine levels in patients blood

Timepoint
In onset of study and days 2, 7 and 14 after the second injection

Method of measurement
Using Elisa kits

3

Description
Cell markers and populations

Timepoint
In onset of study and days 2, 7 and 14 after the second injection

Method of measurement
Using Flow cytometery technique

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group receiving mesenchymal stem cells. In this group, patients in 3 times (1, 3 and 6 days) are received 1 million Umbilical core-derived MSCc/BW by intravenous injection (Through the catheter and the Central vein and from the superior vena cava vein).

Also, in addition to cell therapy,Other common treatments will be given to patients according to the physician's supervision.Mesenchymal Stem cells had an ISCT standard and were given from a healthy donor. Blood samples were given from patients on days 0, 2, and 7, as well as 14 days after the second injection and patients will follow for 20 days (in terms of clinical and immunological parameters).It should be noted that of all patients at the beginning of the study conscious consent form will be received.

Category

Treatment - Surgery

2

Description

Control group: Receiving common therapies (without stem cell). In this group, patients are received other common treatments including antiviral drugs and etc In accordance with the physician's opinion and do not receive stem cells.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Dr.Mahnaz Amini

Street address

Dr.Shariati square

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Quaem.Medical.center@mums.ac.ir

Web page address

http://nobatdrazavi.tamin.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

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vcresearch@mums.ac.ir

Grant name

Grant provided for COVID 19 projects

Grant code / Reference number

981880

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

70

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

2

Sponsor

Name of organization / entity

Parnia stem cell Knowledge-based company

Full name of responsible person

Seyed jalil tavakol afshari

Street address

Kafai 1, Sadra Medical Building

City

Mashhad

Province

Razavi Khorasan

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Email

Parnia@mums.ir

Web page address

Grant name

Parnia-COVID19

Grant code / Reference number

پرنیا 19

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Parnia stem cell Knowledge-based company

Proportion provided by this source

30

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Seyad Jalil Tavakol Afshari

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Stem cell therapy

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Bu-Ali square, Bu-Ali Science and Technology Park

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Person responsible for scientific inquiries

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Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Immunology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
Immunology

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available