Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparison Study on Safety & Efficacy of Repeated Intravenous Infusion of Allogeneic Mesenchymal Stem Cell from Different Sources in ARDS Patients: A Randomized, Double Blind, Clinical Trial Phase II

Protocol summary

Study aim

Safety of 3 Times Intravenous Transplantation of Allogeneic Different Sources Derived-Mesenchymal Stem Cells in ARDS Patients

Design

A uncontrolled, parallel, double-blind, randomized, clinical trial, phase II 4 groups, 3 patients in each group, totally 12 patients 4 cell interventional groups 12 months follow-up

Settings and conduct

We carry out a randomized, double-blind phase II trial of 3 times Intravenous infusion of allogeneic mesenchymal stem cells derived from different sources for treatment in 12 ARDS patients, 3 bone marrow derived MSC, 3 adipose derived MSC, 3 wharton's jelly derived MSC and 3 amniotic membrane derived MSC, in a 1:1:1:1 randomization. Each patient receives 3 Intravenous infusions every other day. Patients will be followed daily during 7 days after the first transplantation, Then at 2 week, 4 weeks, 3, 6 and 12 months. Three doses of 200×10#6 cells are intravenously infused as a naturally dropped single dose over 15-20 minutes in every other day. The cell products will be supplied by CELLTECH company and Royan institute. The products will be transferred to Baqiyatallah hospital and transplanted.

Participants/Inclusion and exclusion criteria

• Aged between 18 to 65 years • Male or female • Signed informed consent voluntarily • Confirmed ARDS

Intervention groups

First Intervention group: Wharton's jelly derived mesenchymal stem cells Second Intervention group: Amniotic membrane derived mesenchymal stem cells Third Intervention group: Bone marrow derived mesenchymal stem cells Forth Intervention group: Adipose derived mesenchymal stem cells

Main outcome variables

Numbers of Patients Occurred Any Unexpected Severe Adverse Events (Including All-cause Deaths)

General information

Reason for update

Acronym

Allo-MSCs-ARDS

IRCT registration information

IRCT registration number: **IRCT20080901001165N44**
Registration date: **2020-03-28, 1399/01/09**
Registration timing: **prospective**

Last update: **2020-03-28, 1399/01/09**
Update count: **0**

Registration date

2020-03-28, 1399/01/09

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-29, 1399/01/10

Expected recruitment end date

2020-08-31, 1399/06/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparison Study on Safety & Efficacy of Repeated Intravenous Infusion of Allogeneic Mesenchymal Stem Cell from Different Sources in ARDS Patients: A Randomized, Double Blind, Clinical Trial Phase II

Public title
A Comparison Study of Repeated Intravenous Infusion of Allogeneic Mesenchymal Stem Cell from Different Sources in ARDS Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Signed informed consent voluntarily Confirmed ARDS SOFA score between 2-3 point PaO2/FIO2 ≤ 300 mmHg Mild to Moderate pneumonia/ stay in the ICU <48 hours Pulmonary imaging shows that the focus progress > 50% in 24-48 hours
Exclusion criteria:
Co-Infection of HIV, tuberculosis, influenza virus, adenovirus and other respiratory infection virus Liver or kidney SOFA score of more than 3 points; combined with other organ failure Patients with malignant tumor Pregnant or lactating women Uncontrolled underling diseases Pulmonary obstructive pneumonia, severe pulmonary interstitial fibrosis, allergic alveolitis, and other known viral pneumonia or bacterial pneumonia In vitro life support (ECMO, ECCO2R, RRT)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **12**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
There are the same cell bags for infusion during study. Clean room staff, DSMB and data statistician just aware of their contain. So, the mentioned people (clinicians for assessment, health care system staff for infusion and patients) will not inform about the type of intervention.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Institute for Medical Research Development
Street address
No. 21, Besat Ave, West Fatemi Ave, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۶۹۳۱۱۱
Approval date
2020-03-25, 1399/01/06
Ethics committee reference number
IR.NIMAD.REC.1399.002

Health conditions studied

1

Description of health condition studied
Acute respiratory distress syndrome (ARDS)
ICD-10 code
J80
ICD-10 code description
Acute respiratory distress syndrome

Primary outcomes

1

Description
Numbers of Patients Occurred Any Unexpected Severe Adverse Events (Including All-cause Deaths)
Timepoint
Before Intervention, Day 0 (First Intervention) till Day 7, Day 14, Day 28, 3 Moths, 6 Months and 12 months after intervention
Method of measurement
Fill Common Terminology Criteria for Adverse Events (CTCAE) Form

Secondary outcomes

1

Description
PaO2/FiO2 assessment
Timepoint
Before Intervention, Day 0 (First Intervention) till Day 7, Day 14, Day 28, 3 Moths, 6 Months and 12 months after

intervention

Method of measurement

Ventilator

Intervention groups

1

Description

First Intervention group: Wharton's jelly derived mesenchymal stem cells

Category

Treatment - Drugs

2

Description

Second Intervention group: Amniotic membrane derived mesenchymal stem cells

Category

Treatment - Drugs

3

Description

Third Intervention group: Bone marrow derived mesenchymal stem cells

Category

Treatment - Drugs

4

Description

Forth Intervention group: Adipose derived mesenchymal stem cells

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiyyatollah hospital

Full name of responsible person

Dr. Mostafa Ghanei

Street address

Mollasadra Ave, after Sheikh Bahaei cross, Vanak square, Tehran

City

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Province

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Postal code

1435915371

Phone

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Web page address

https://baq.bmsu.ac.ir/Portal/Home/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr.Mostafa Ghanei

Street address

Mollasadra Ave, after Sheikh Bahaei cross, Vanak square, Tehran

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Province

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1435915371

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Email

mghaneister@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

National Institute for Medical Research Development

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Hoda Madani

Position

Co-PI

Latest degree

Medical doctor

Other areas of specialty/work

Medical Biology

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mostafa Ghanei
Position
professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Case Report Form
When the data will become available and for how long
Start of access period 6 months after printing results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
complementary studies related to cell products
From where data/document is obtainable
Email to corresponding author
What processes are involved for a request to access data/document
Reply to email by corresponding author (1 week) After confirmation, data files will be sent less than two weeks
Comments