

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of safety and efficacy of allogeneic adipose-derived mesenchymal stem cell administration in Bronchiolitis Obliterans Syndrome (BOS) after allogeneic hematopoietic stem cell transplantation.

Protocol summary

Study aim

1) Evaluation of mesenchymal stem cell administration's safety in patients with bronchiolitis obliterans syndrome after hematopoietic stem cell transplantation. 2) Evaluation of the effectiveness of mesenchymal stem cell administration in patients with bronchiolitis obliterans syndrome after hematopoietic stem cell transplantation.

Design

Single-arm non-randomized clinical trial (a pilot study).

Settings and conduct

1) Patients selection. 2) laboratory and pulmonary function tests for evaluation of bronchiolitis obliterans. 3) obtaining consent forms from patients' guardians. 4) manufacture of mesenchymal stem cells from adipose tissue. 5) administration of mesenchymal stem cells. 6) patients follow up and evaluations. 7) Record and publish data.

Participants/Inclusion and exclusion criteria

Patients under 16 years, transplantation has been done over the past year, FEV1<70% in spirometry, corticosteroid-resistant patients, absence of other concomitant infections.

Intervention groups

Intravenous injection of mesenchymal stem cells 1 million per kg for each individual patient.

Main outcome variables

Safety and efficacy of mesenchymal stem cell administration in patients with bronchiolitis obliterans.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201202049568N2**

Registration date: **2021-02-22, 1399/12/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-22, 1399/12/04**

Update count: **0**

Registration date

2021-02-22, 1399/12/04

Registrant information

Name

Rashin Mohseni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 8444

Email address

rashin_mohseni@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

2020-12-21, 1399/10/01

Actual recruitment end date

2022-08-23, 1401/06/01

Trial completion date

2022-08-23, 1401/06/01

Scientific title

Evaluation of safety and efficacy of allogeneic adipose-derived mesenchymal stem cell administration in Bronchiolitis Obliterans Syndrome (BOS) after allogeneic hematopoietic stem cell transplantation.

Public title

Safety and efficacy of Mesenchymal Stem Cell administration in Bronchiolitis Obliterans Syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age below 16 years Allogeneic hematopoietic stem cell transplantation (HSCT) over the past year Forced Expiratory Volume in one second (FEV1) < 70 % (based on Pulmonary Function Test) Diagnosis of BOS in end-stage phase with the history and clinical evaluation by a pediatric pulmonologist, and the presence of air-trapping or small airway involvement in high-resolution computed tomography (HRCT) Absence of concomitant infections Irresponsible to full-dose corticosteroids Give the informed consent by the patients' legal guardians

Exclusion criteria:

Suspicion to any bacterial or viral pneumonia CMV, VZV, HSV and/or fungal pneumonia Haploidentical and/or T-cell deplete transplantation Prior history of allergy or sensitivity to drugs Relapse or progression of underlying malignancy

Age

From **1 month** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Actual sample size reached: **10**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Pilot study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran university of medical science

Street address

e.g. Children medical centre., Dr Gharib Ave., Keshavarz Blvd., Tehran., Iran.

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2020-09-05, 1399/06/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.406

Health conditions studied

1

Description of health condition studied

bronchiolitis obliterans

ICD-10 code

J84.115

ICD-10 code description

Respiratory bronchiolitis interstitial lung disease

Primary outcomes

1

Description

Forced expiratory volume in one second (FEV1)

Timepoint

Before intervention and then 1,3,6 months after intervention.

Method of measurement

Pulmonary Function Test (Spirometry)

2

Description

FEV1/FVC ratio

Timepoint

Before intervention and then 1,3,6 months after intervention.

Method of measurement

Pulmonary Function Test (Spirometry)

Secondary outcomes

1

Description

Fractional exhaled nitric oxide (FeNO)

Timepoint

Before intervention and then 1,3,6 months after intervention.

Method of measurement

FeNO test

Intervention groups

1

Description

Intervention group: mesenchymal stem cells from the donors' adipose tissue will be extracted and then cultured in the laboratory. Final products will be injected

with a dosage of 1 million per kg intravenously to the patients. All the patients will be hospitalized for 24 hours for further observation.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children's medical centre

Full name of responsible person

Amirali hamidieh

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Children's medical centre., Gharib avenue., Keshavarz Blvd., Tehran., Iran.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Web page address**Grant name****Grant code / Reference number**

98-3-421-46134

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

28

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**

Council for Development of Stem Cell Sciences and Technologies

Full name of responsible person

Amir Ali Hamidieh

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Council for Development of Stem Cell Sciences and Technologies

Proportion provided by this source

28

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**

Academic

3**Sponsor****Name of organization / entity**

Omid charity

Full name of responsible person

Alireza Daliri

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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
 Omid charity
Proportion provided by this source
 44
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
 Tehran University of Medical Sciences
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 Rashin Mohseni
Position
 PhD in Applied Cell Science
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data regarding the primary and secondary outcomes without any identifiable personal data will be shared.

When the data will become available and for how long

Six months after the publication of the results of this study

To whom data/document is available

Investigators in academic institutions.

Under which criteria data/document could be used

Medical doctors or scientists who are conducting studies in the same subject including mesenchymal stem cell therapy or bronchiolitis obliterans.

From where data/document is obtainable

The data that support the findings of this study will be available on request from the corresponding author. The data will not be publicly available due to privacy and ethical considerations.

What processes are involved for a request to access data/document

The data that support the findings of this study will be available on request from the corresponding author. The data will not be publicly available due to privacy and ethical considerations.

Comments