Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Determination of the safety of using allogeneic mesenchymal stem cells by pilot method in patients with cystic fibrosis referred to the Children's Medical Center

Protocol summary

Study aim
Determining the safety of use of allogeneic mesenchymal stem cell in cystic fibrosis patients

Design
Double-blind randomized clinical trial with control and parallel groups

Settings and conduct
10 patients with definite diagnosis of cystic fibrosis referred to Tehran Children's Medical Center Hospital will be included in the study according to inclusion and exclusion criteria. Eligible people will be randomly divided into two groups of 5 people. Everyone will be tested for PFT and 6MWT. 5 patients received placebo as a single dose in the peripheral vein and 5 patients with a dose of 20 million cells as a single dose. In the peripheral vein, human allogeneic mesenchymal stem cells will be injected. Patients will be evaluated for side effects up to 30 days after injection. Then, at the end of the year, the tests that were performed at the beginning of the study as basic tests will be repeated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: severe obstructive disease defined as FEV1 / FVC less than 50%; acceptable function of other organs including creatinine level less than 1.5 times normal limit; ALT level less than 135; AST level less than 3 times normal limit; normal heart function on echo cardiogram; patients in the age range of 12 to 18 years old. Exclusion criteria: the presence of any viral or bacterial infection that has caused pneumonia; patients with Heart Failure; patients with mental and physical disabilities.

Intervention groups
Patients with cystic fibrosis were randomly divided into placebo and intervention groups.Five patients were injected single-dose placebo into a peripheral vein, and another 5 patients were injected into a peripheral human allogeneic mesenchymal stem cell, or Allo-hMSC for short, at a dose of 20 million cells per single dose.

Main outcome variables
Pulmonary function tests Body Mass Index six minute walking test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211110053033N1**
Registration date: **2022-01-02, 1400/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-02, 1400/10/12**
Update count: **0**

Registration date
2022-01-02, 1400/10/12

Registrant information

Name
Faezeh Bolboli

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 4422 4526

Email address
faezeh.bolboli@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-26, 1400/10/05

Expected recruitment end date
2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of the safety of using allogeneic mesenchymal stem cells by pilot method in patients with cystic fibrosis referred to the Children's Medical Center

Public title

Determination of safety of allogeneic mesenchymal stem cells by pilot method in patients with cystic fibrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of cystic fibrosis Severe obstructive disease defined as FEV1 / FVC less than 50% Acceptable function of other organs including creatinine level less than 1.5 times normal limit in each age group, ALT level less than 135, AST level less than 3 times normal limit in each age group, bilirubin level less than 1.5 times Normal limit in any age group Normal heart function on echocardiogram Patients in the age range of 12 to 18 years

Exclusion criteria:

The presence of any viral or bacterial infection that has caused pneumonia Patients with Heart Failure Patients with mental and physical disabilities

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized numbers from one to 10 was produced with a calculator, the first five numbers allocated to intervention group and the other five numbers allocated to control group.Then drugs sequentially from 1 to 10, was given to researcher for prescription to the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs and placebos are the same in terms of appearance, color, etc., and thus patients and researchers will not know the contents.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Children's Medical Center, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

14197 33151

Approval date

2021-07-07, 1400/04/16

Ethics committee reference number

IR.TUMS.CHMC.REC.1400.073

Health conditions studied

1

Description of health condition studied

Cystic fibrosis

ICD-10 code

E84

ICD-10 code description

Cystic fibrosis

Primary outcomes

1

Description

Lung Volume (Forced expiratory volume in one second);(FEV1)

Timepoint

At the first visit and follow-up for up to a year

Method of measurement

Spirometry

2

Description

Lung Volume (Forced Vital Capacity); (FVC)

Timepoint

At the first visit and follow-up for up to a year

Method of measurement

Spirometry

3

Description

Lung Volume (Forced Expiratory flow 25_75%); (FEF25-75%)

Timepoint
At the first visit and follow-up for up to a year
Method of measurement
Spirometry

4

Description
Forced expiratory volume in 1 second to forced vitalcapacity (FEV1/FVC)
Timepoint
At the first visit and follow-up for up to a year
Method of measurement
Spirometry

5

Description
Walking distance upon 6 minute walking distance test(meter)
Timepoint
At the first visit and follow-up for up to a year
Method of measurement
Six minute walking distance test

6

Description
Body Mass Index
Timepoint
At the first visit and follow-up for up to a year
Method of measurement
Weight (kilogram) divided by height squared (centimetre)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In 5 patients with cystic fibrosis in the peripheral vein, human allogeneic mesenchymal stem cells (Allo-hMSC) will be injected in a single dose of 20 million cells.
Category
Treatment - Drugs

2

Description
Control group: In 5 patients with cystic fibrosis, the placebo will be injected as a single dose into the peripheral vein.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Children's Medical Center
Full name of responsible person
Mohammadreza Modarresi
Street address
Keshavarz Blvd
City
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Postal code
14197 33151
Phone
+98 21 6147 0000
Email
mohammadreza.modaresi@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Central Campus of the University of Tehran, Vice Chancellor for Research, 16 Azar St., Enghelab St., Enghelab Square
City
Tehran
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Postal code
1417614411
Phone
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resaerch@ut.ac.ir
Grant name
Grant code / Reference number
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
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
Tehran University of Medical Sciences

Full name of responsible person
Faezeh Bolboli

Position
Lung Specialist Assistant

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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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
Information on the main outcome or the like can be shared.

When the data will become available and for how long
Available access 9 months after the publication of results

To whom data/document is available
no

Under which criteria data/document could be used
no

From where data/document is obtainable
Dr. Faezeh Bolboli

What processes are involved for a request to access data/document
Communicating with the person in charge

Comments