

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)

Phone

+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

Tehran

Province

Tehran

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

Province

Tehran

Postal code

1417614411

Phone

+98 21 6649 8813

Email

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

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

14197 33151

Phone

+98 21 6147 0011

Email

faezeh.bolboli@gmail.com

Person responsible for scientific 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

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

14197 33151

Phone

+98 21 6147 0011

Email

faezeh.bolboli@gmail.com

Person responsible for updating data

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

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

14197 33151

Phone

+98 21 6147 0011

Email

faezeh.bolboli@gmail.com

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