

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The survey of efficacy of intracoronary autologous bone marrow-derived mononuclear stem cell injection in treatment of children with dilated cardiomyopathy (The third phase of clinical trial)

#### Protocol summary

##### Study aim

Determining the profitability of intracoronary stem cell injection for dilated cardiomyopathy in children

##### Design

Approximately 10 patients with cardiomyopathy ,non responding to drug treatment, are referred every year. two-dimensional echo and color Doppler, Tissue Doppler and Speckle Tracking Echocardiography will be recorded. In the morning, a bone marrow aspiration sample will be taken. According to the protocol provided by the Stem Cell Center of Shiraz University of Medical Sciences, the sample will be transferred to the mother and child hospital in a suitable culture medium for isolation of stem cells. The solution for injection, containing at least 20 million stem cells, will be returned to the hospital of origin following a cold chain. The cells are injected on angiography on the same day.

##### Settings and conduct

pediatric cardiology ward , Namazi hospital

##### Participants/Inclusion and exclusion criteria

Patients choose from all cases of dilated cardiomyopathy without a known cause who have not responded to the usual routine anti failure treatments and have frequent hospitalizations or dependence on injectable cardiac inotropic drugs in their last hospitalization for more than 2 weeks. if the study conditions are accepted, they will be included in the list of patients.

##### Intervention groups

Selective coronary angiogram is performed and after determining the path of coronary arteries by an over the wire balloon, the initial part of each of the three main coronaries LAD, LCX and RCA is temporarily tight for less than 2 to 3 minutes based on ECG changes. (To reduce the speed of coronary blood flow and increase the residence time of the solution containing cells in the coronary tract) and 3 cc of the prepared solution is injected at low speed.

#### Main outcome variables

Cardiac function is monitored by ejection fraction and spike tracking

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100212003331N2**

Registration date: **2022-01-19, 1400/10/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-19, 1400/10/29**

Update count: **0**

##### Registration date

2022-01-19, 1400/10/29

##### Registrant information

##### Name

Hamid Amoozgar

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1626 9047

##### Email address

amozgah@sums.ac.ir

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2022-01-08, 1400/10/18

##### Expected recruitment end date

2027-01-08, 1405/10/18

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The survey of efficacy of intracoronary autologous bone marrow-derived mononuclear stem cell injection in treatment of children with dilated cardiomyopathy (The third phase of clinical trial)

**Public title**  
The survey of efficacy of intracoronary autologous bone marrow-derived mononuclear stem cell injection in treatment of children with dilated cardiomyopathy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age between 1 to 18 years - Definitive diagnosis of dilated cardiomyopathy without a treatable cause (arrhythmia - ALCAPA - tumors, etc.) Lack of response to maximum oral antifailure treatments and the need for frequent hospitalization or dependence on injectable inotropes4 Lack of response to maximum oral antifailure treatments and the need for frequent hospitalization or dependence on injectable inotropes4- Normal kidney function and no serious functional liver damage (INR> 2 - Alb <3 - AST, ALT more than 3 times of NI Range). - no hematological disorders No syndromic diseases Accepting the participation form in the study and being aware of the side effects of this treatment - If the initial response is appropriate, increase the EF by 5% in the first injection of the second injection, 3 months after the first injection.

**Exclusion criteria:**

Non-compliance with any of the entry conditions at each stage of the study before stem cell injection Not accepting the informed consent form to participate in the study or performing cardiac angiography. Appropriate response to oral antifailure treatment Active infection Less than 6 months have passed since the diagnosis of dilated cardiomyopathy Existence of refractory arrhythmia due to dilated cardiomyopathy Existence of bleeding and serious coagulation disorder

**Age**  
From **1 year** old to **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **10**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used  
**Assignment**  
Single  
**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Namazi hospital, Zand BLV

**City**

Shiraz

**Province**

Fars

**Postal code**

1331171936

**Approval date**

2022-01-06, 1400/10/16

**Ethics committee reference number**

IR.SUMS.REC.1400.709

**Health conditions studied**

**1**

**Description of health condition studied**

Cardiomyopathy

**ICD-10 code**

I42.0

**ICD-10 code description**

Dilated cardiomyopathy

**Primary outcomes**

**1**

**Description**

Ejection fraction

**Timepoint**

baseline, 1mo, 3 mo, 6mo

**Method of measurement**

Echocardiography

**2**

**Description**

6 Min walk test

**Timepoint**

baseline, 1mo, 3 mo, 6mo

**Method of measurement**

Test in pediatric cardiology ward

### **3**

#### **Description**

speckle echocardiography

#### **Timepoint**

baseline, 1mo, 3 mo, 6mo

#### **Method of measurement**

echocardiography

#### **Secondary outcomes**

empty

#### **Intervention groups**

### **1**

#### **Description**

Patients choose from all cases of dilated cardiomyopathy without cause or due to myocarditis who have not responded well to the usual routine antifailure treatments and have frequent hospitalizations or dependence on injectable cardiac inotropic drugs in their last hospitalization for more than 2 weeks. And if the study conditions are accepted and the possible complications of angiography and this treatment are announced, they will be included in the list of patients. For 5 years, all patients who meet the entry requirements will enter the plan and their information will be collected. Approximately every year, about 10 patients with the specified conditions are referred to Shiraz hospitals. Patients with eligibility will be admitted to the pediatric cardiology department and two-dimensional echo and color Doppler, Tissue Doppler and Speckle Tracking Echocardiography will be recorded before the patient is injected and the patient will be examined for coagulation, liver, kidney and clot tests. If possible, a 6-minute walk test will also be performed. In the morning, a bone marrow aspiration sample will be taken in the morning in collaboration with the Pediatric Hematology Fellowship. According to the protocol provided by the Stem Cell Center of Shiraz University of Medical Sciences, the sample will be transferred to the mother and child hospital in a suitable culture medium for isolation of stem cells in the clean room of this hospital (Clean Room). In this center, the process of preparation and isolation of cells under aseptic conditions will be performed by the colleagues of the Stem Cell Institute, and the solution for injection in a volume of 10 cc and containing at least 20 million stem cells will be returned to the hospital of origin with cold chain (this process It takes about 4 hours and the cells are injected on angiography on the same day, and a panel of different antibodies is placed to identify the cell surface markers. Checking the specifications and identifying the prototype (bone marrow): All bone marrow cells are immature, multivalent cells that originate from a common common ancestral cell. These cells are precursors to various classes of hematopoietic cells as well as non-hematopoietic stem cells, including endothelial progenitor cells and mesenchymal stem cells in small numbers. Naturally, these cells lack the specific markers of differentiated cells. In order to check the

characteristics and identify the prototype (bone marrow), panels of different antibodies were placed, which are briefly mentioned. The results of the analysis were checked by BD FACS Calibur flow cytometer and read using CellQuest Pro software. (Complete results with specifications and identification analysis are also available if required). Panel 1: Marker of immature T lymphocyte cell line CD3: 11.4% CD13: 3.72% Panel 2: Marker of immature B lymphocyte cell line CD10: 1.00% CD20: 5.22% CD45: 30.8% Panel No. 3: Multivalent Stem Cell Marker CD34: 0.317% CD117: 0.272% CD45: 55.2% Specification and identification of the final cell product: Since all cells in the bone marrow, including mononuclear cells, are responsible for producing lymphoid blood cell lines and monocytes, as well as non-hematopoietic stem cells, including mesenchymal stem cells, They are immature, polyvalent cells that originate from a common common ancestral cell. Therefore, they do not have specific markers of differentiated blood cells. To evaluate the characteristics and identify the cellular product, panels of different antibodies were placed, which are briefly mentioned. (Complete results with specifications and identification analysis are also available if required). Panel 1: Marker of immature T lymphocyte cell line CD3: 62.0% CD13: 18.0% Panel 2: Marker of immature B lymphocyte cell line CD10: 2.82% CD20: 8.59% CD45: 77.70% Panel No. 3: Multivalent Stem Cell Marker CD34: 0.754% CD117: 0.709% CD45: 82.9% Selective coronary angiogram is performed and after determining the path of coronary arteries by an over the wire balloon, the initial part of each of the three main coronaries LAD, LCX and RCA is temporarily tight for less than 2 to 3 minutes based on ECG changes. (To reduce the speed of coronary blood flow and increase the residence time of the solution containing cells in the coronary tract) and 3 cc of the prepared solution is injected at low speed. All patients will be monitored for ECG changes and cardiac enzymes for up to 24 hours during and after the procedure. Hospitalization of patients continues until a completely stable clinical condition develops. Subsequent follow-ups of patients will be based on ECG, 2D echo and color Doppler + Tissue Doppler and Speckle tracking echo at intervals of 3 months, 6 months and 12 months. Follow-up results and patients' performance class will be recorded on Form One. At the end of one year of follow-up, patients will be statistically evaluated

#### **Category**

Treatment - Other

#### **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Namazi hospital, pediatric cardiology ward

##### **Full name of responsible person**

Hamid Amoozgar

##### **Street address**

Zand BLV

##### **City**

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dramoozgar@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
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amozgah@sums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shiraz 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**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Hamid Amoozgar  
**Position**

Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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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**

Exel

**When the data will become available and for how long**

3 years

**To whom data/document is available**

For university researches

**Under which criteria data/document could be used**

request of researchers

**From where data/document is obtainable**

Hamid Amoozgar

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

request form

**Comments**