Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 71 1626 9047

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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 Nl 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 lineCD3: 11.4%CD13: 3.72%Panel 2: Marker of immature B lymphocyte cell lineCD10: 1.00%CD20: 5.22%CD45: 30.8%Panel No. 3: Multivalent Stem Cell MarkerCD34: 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 lineCD3: 62.0%CD13: 18.0%Panel 2: Marker of immature B lymphocyte cell lineCD10: 2.82%CD20: 8.59%CD45: 77.70%Panel No. 3: Multivalent Stem Cell MarkerCD34: 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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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
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