

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Safety Assessment of Intracoronary Transplantation of Autologous Bone Marrow Derived Mononuclear Cells in Pediatric with Dilated Cardiomyopathy in Comparison with Control Group: Clinical Trial Phase I/II

Protocol summary

Study aim

Assessment of safety and tolerability

Design

A controlled, parallel, randomized, open label clinical trial, phase I/II on 24 patients

Settings and conduct

Location: Royan Institute and Rajaie Cardiovascular, Medical and Research Center After enrollment, patients are randomly divided into 2 groups of cell and control. only patients which in cell group undergo bone marrow biopsy and their bone marrow-derived mononuclear cells (MNCs) are isolated and transferred to the relevant hospital in special containers and under sterile conditions and are used for injection into the coronary arteries. Patients in both groups are followed up at specific times and the data are evaluated using software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 1-16 year (s) Both sex LVEF<45% (echocardiography) Time of Diagnosis > 3m Resistance to Standard therapy > 1m (Dig, ACEi, Diuretic, BB) Informed consent Exclusion criteria: Congenital heart disease Active infection less than one month Dysrhythmia Cardiogenic shock Renal failure

Intervention groups

1- Recipient group of autologous bone marrow derived mononuclear cells 2- Control group (with no intervention)

Main outcome variables

Adverse events

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080728001031N27**

Registration date: **2021-01-10, 1399/10/21**

Registration timing: **retrospective**

Last update: **2021-01-10, 1399/10/21**

Update count: **0**

Registration date

2021-01-10, 1399/10/21

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

nasser.aghdami@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-05-01, 1392/02/11

Expected recruitment end date

2016-03-29, 1395/01/10

Actual recruitment start date

2014-10-01, 1393/07/09

Actual recruitment end date

2016-12-29, 1395/10/09

Trial completion date

2018-03-20, 1396/12/29

Scientific title

Safety Assessment of Intracoronary Transplantation of Autologous Bone Marrow Derived Mononuclear Cells in Pediatric with Dilated Cardiomyopathy in Comparison

with Control Group: Clinical Trial Phase I/II

Public title
Effect of bone marrow derived mononuclear cells in treatment of pediatric with cardiomyopathy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
LVEF<45% (echocardiography) Time of Diagnosis > 3m
Resistance to Standard therapy > 1m (Dig, ACE, Diuretic, BB)
Exclusion criteria:
Critical aortic stenosis Severe coarctation Coronary artery anomalies Cardiogenic shock

Age
From **1 year** old to **16 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Random number table was provided by statistician using randomization website (block randomization with block size of 4) according to individual unit and allocation was performed by a third party which is not directly connected with the clinical trial.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Royan Institute

Street address

Royan Alley, Eastern Hafez St, Northern Banihashem St, 45 m Ghasem Soleymani Highway

City

Tehran

Province

Tehran

Postal code

1665664511

Approval date

2012-04-15, 1391/01/27

Ethics committee reference number

K/91/1152

Health conditions studied

1

Description of health condition studied

Dilated cardiomyopathy

ICD-10 code

I42.0

ICD-10 code description

Dilated cardiomyopathy

Primary outcomes

1

Description

Assessment of safety and tolerability

Timepoint

3 months

Method of measurement

Physical examination and clinical symptom

Secondary outcomes

1

Description

ProBNP measurement

Timepoint

0, 2 weeks, 1, 2, 4 and 6 months

Method of measurement

Lab test

Intervention groups

1

Description

Intervention group: This group underwent bone marrow aspiration in amount of 2 cc/kg. This sample transfers to clean room of Royan institute for mononuclear cells processing. Then, patients underwent coronary angiography in less than 6 hours and these cells which are suspended in 10 cc of normal saline will be infused intracoronary.

Category

Treatment - Other

2

Description

Control group: This group do not underwent bone marrow aspiration and do not receive placebo. So, they are as a comparison group.

Category

N/A

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Dr Seyed Mohammad Mahdavi

Street address

Niyayesh ave crossroad, Valiasr st.

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Email

md_niaki@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Abdolhossein shahverdi

Street address

Royan Alley, Eastern Hafez St, Northern Banihashem
St, 45 m Ghasem Soleymani Highway

City

Tehran

Province

Tehran

Postal code

1665664511

Phone

+98 21 2356 2000

Email

shahverdi@royaninstitute.org

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Royan Institute

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

Person responsible for general inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Hoda Madani

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Cell science and application

Street address

Royan Alley, Eastern Hafez St, Northern Banihashem
St, 45 m Ghasem Soleymani Highway

City

Tehran

Province

Tehran

Postal code

1665664511

Phone

+98 21 2251 8388

Email

hoda62_m@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Nasser Aghdami

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

Street address

Royan Alley, Eastern Hafez St, Northern Banihashem
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City

Tehran

Province

Tehran

Postal code

1665664511

Phone

+98 21 2251 8388

Email

nasseragh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Hoda Madani

Position

M.D/Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Cell science and application

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available