Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 lass than 6 hours and theses 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

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

Type of organization providing the funding
Academic

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 St, 45 m Ghasem Soleymani Highway

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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Province

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Email

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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