

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety Assessment of Intracoronary Transplantation of Wharton's Jelly Derived-Mesenchymal Stem Cells in Pediatric with Non-Ischemic Dilated Cardiomyopathy: Clinical Trial Phase I

Protocol summary

Study aim

Assessment of safety and tolerability

Design

uncontrolled, single arm, unblinded, not randomized clinical trial phase I on 5 patients

Settings and conduct

Location: Children's Medical Center and Royan Institute
In this study, 5 eligible patients with dilated cardiomyopathy due to viral myocarditis underwent single intracoronary infusion of (1.5×10⁶/Kg) wharton's jelly derived-mesenchymal stem cells which are suspended in 5- 10 cc normal saline. These cells provide from a GMP certified bank. The patients will transfer to ICU or CCU. Then, they follow up at defined timepoints (1 week, 1,3,6,9 and 12 months) and data will be documented and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Age 4-12 y 2-Both sex 3-20% <LVEF<35% (echocardiography) 4- Time of Diagnosis > 1 y 5-Candidate for heart transplantation 6-Heart failure due to idiopathic and acute viral myocarditis 7-NYHA function class II/III Exclusion criteria: 1-Critical aortic stenosis 2- Severe coarctation 3- Coronary artery anomalies 4- Cardiogenic shock

Intervention groups

Interventional group: The group receive single intracoronary infusion of (1.5×10⁶/Kg) of wharton's jelly derived-mesenchymal stem cells which is suspended in 5-10 cc normal saline. This study has no control group.

Main outcome variables

Assessment of frequency of adverse event; Assessment of feasibility; Blood test of ProBNP measurement;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201217049743N1**

Registration date: **2021-01-29, 1399/11/10**

Registration timing: **prospective**

Last update: **2021-01-29, 1399/11/10**

Update count: **0**

Registration date

2021-01-29, 1399/11/10

Registrant information

Name

Aliakbar Zeinaloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6147 9000

Email address

zeinaloo@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety Assessment of Intracoronary Transplantation of Wharton's Jelly Derived-Mesenchymal Stem Cells in

Pediatric with Non-Ischemic Dilated Cardiomyopathy:
Clinical Trial Phase I

2020-12-13, 1399/09/23

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.896

Public title

Effect of wharton's jelly derived-mesenchymal stem cells
in treatment of pediatric with cardiomyopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20% <LVEF<35% (echocardiography) Time of Diagnosis
> 1 y Candidate for heart transplantation Heart failure
due to idiopathic and acute viral myocarditis NYHA
function class II/III

Exclusion criteria:

Critical aortic stenosis Severe coarctation Coronary
artery anomalies Cardiogenic shock

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **5**

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 Tehran university of medical
sciences

Street address

Headquarters of Tehran University of Medical
Sciences, Corner of Ghods St., Keshavarz Blvd,
Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

Health conditions studied

1

Description of health condition studied

Viral cardiomyopathy

ICD-10 code

B33.24

ICD-10 code description

Viral cardiomyopathy

Primary outcomes

1

Description

Assessment of safety

Timepoint

Base and 1 week, 1,3,6,9 months after transplantation

Method of measurement

Physical examination and clinical symptom

2

Description

Assessment of tolerability

Timepoint

Base and 1 week, 1,3,6,9 months after transplantation

Method of measurement

Physical examination and clinical symptom

Secondary outcomes

1

Description

ProBNP measurement

Timepoint

Base, 1, 3, 6, 9 and 12 months after transplantation

Method of measurement

Lab test

Intervention groups

1

Description

Intervention group: Wharton's jelly derived-mesenchymal
stem cells receive from a GMP certified bank in Celltech
pharmed Co. Then, patients underwent coronary
angiography and these cells which are suspended in
5-10 cc of normal saline will be infused intracoronary.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center Hospital

Full name of responsible person

Aliakbar Zeinaloo

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Gharib St, Keshavarz Blvd, Tehran

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zeinaloo@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Celltech pharmed company

Full name of responsible person

Mohammad Hosein Ziraksaz

Street address

Celltechpharmed Co., Tolid Darou Pharmaceutical
Complex, Kermany st., Moallem Blv., Yaftabad.
Tehran, Iran

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Province

Tehran

Postal code

1371616312

Phone

+98 21 6735 7000

Email

info@celltech.co

Web page address

<http://celltech.ir/en/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Celltech pharmed company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

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

Applied cell sciences

Street address

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

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Aliakbar Zeinaloo

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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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

Applied cell sciences

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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