

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Determining the effect of stem cell injection on clinical symptoms and echocardiographic findings of children with primary pulmonary artery hypertension

Protocol summary

Study aim

Determining the effect of stem cell injection on clinical symptoms and echocardiographic findings of children with primary pulmonary artery hypertension

Design

A number of 20 children and adolescents with primary pulmonary hypertension will be included in the study. They will be subjected and controlled by simple randomization in two groups of 10 people. The secondary causes of pulmonary hypertension and concomitant congenital heart disease are conditions for exclusion from the study.

Settings and conduct

In the control group, endothelial receptor inhibitor (Liratan) is prescribed at a dose of 0.1 mg per body weight daily. In the intervention group, in addition to the aforementioned standard treatment, stem cells extracted from the dental pulp will be injected according to the protocol. Before and after the injection. At specific time intervals of 24, 72 hours, one and a half months after the injection, clinical parameters (walking capacity in 6 minutes and arterial oxygen saturation), and ecocardiographic finding related to pulmonary hypertension and right ventricular function will be measured and recorded.

Participants/Inclusion and exclusion criteria

Patients aged 3-18 years with primary pulmonary hypertension

Intervention groups

In the intervention group, after temporary hospitalization, processed stem cells are injected to the patients, and for the control group, oral medicine is prescribed on an outpatient basis.

Main outcome variables

pulmonary arterial pressure

General information

Reason for update

Acronym

PAH

IRCT registration information

IRCT registration number: **IRCT20210317050737N2**

Registration date: **2023-02-06, 1401/11/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-06, 1401/11/17**

Update count: **0**

Registration date

2023-02-06, 1401/11/17

Registrant information

Name

Maryam Ahmadipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3247 0346

Email address

m.ahmadipour@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Determining the effect of stem cell injection on clinical symptoms and echocardiographic findings of children with primary pulmonary artery hypertension

Public title
The role of stem cells in the treatment of primary pulmonary hypertension

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients aged 3-8 years diagnosed with primary pulmonary hypertension
Exclusion criteria:
Accompanying congenital heart disease Secondary causes of pulmonary hypertension

Age
From **3 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
With the simple random method, random selection method is used to determine the position of the first sample. Names of patients are written on similar papers and placed in a bag. The first paper is randomly take out from the bag. This number represents the first person who is placed in the stem cell injection group, the patient with the next number enters the drug treatment group and this is repeated in order until the sample volume is complete.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The use of stem cells in the treatment of pulmonary hypertension is currently limited

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Kerman University of Medical Sciences
Street address
Afzalipour Hospital, Emam Blvd, Kerman Town
City
kerman
Province
Kerman
Postal code
7616913355
Approval date
2022-10-30, 1401/08/08
Ethics committee reference number
IR.KMU.AH.REC.1400.181

Health conditions studied

1

Description of health condition studied

Primary pulmonary hypertension

ICD-10 code

I27.0

ICD-10 code description

Primary pulmonary hypertension

Primary outcomes

1

Description

pulmonary arterial pressure

Timepoint

Before injection and after injection at intervals of 24 and 48 hours, one and 6 months later

Method of measurement

Transthoracic echocardiography

2

Description

6 minute walk test

Timepoint

Before injection and after injection at intervals of 24 and 48 hours, one and 6 months later

Method of measurement

Observing and measuring the distance traveled

3

Description

Arterial oxygen saturation percentage

Timepoint

Before injection and after injection at intervals of 24 and 48 hours, one and 6 months later

Method of measurement

Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Stem cell injection of one and a half milliliter per kilogram of the patient's weight from processed stem cells with a concentration of one million stem cells in 200 microliters intravenously and through a peripheral vein.

Category

Treatment - Drugs

2

Description

Control group: Prescription of tadalafil at the rate of 1 milligram per kilogram weight per day for two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Maryam Ahmadipour

Street address

Afzalipour Hospital, Emam Blvd,

City

Kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 2235 0118

Email

maryam.ahmadipour5@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Maryam Ahmadipour

Street address

Afzalipour Hospital, Emam Blvd,

City

kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 2235 0118

Email

maryam.ahmadipour5@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Maryam Ahmadipour

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

Afzalipour Hospital, Emam Blvd

City

Kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 2235 0118

Email

maryam.ahmadipour5@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Maryam Ahmadipour

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

Afzalipour Hospital ,Emam Blvd
City
Kerman
Province
Kerman
Postal code
7616913355
Phone
+98 34 2235 0118
Email
maryam.ahmadipour5@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Maryam Ahmadipour
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Afzalipour Hospital,Emam Blvd
City
Kerman
Province

Kerman
Postal code
7616913355
Phone
+98 34 2235 0118
Email
maryam.ahmadipour5@gmail.com

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