

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A Clinical trial to evaluate the effects of intrapulmonary injection of bone marrow derived mononuclear cells along with pulmonary hypertension drugs on pulmonary pressure in patients with Eisenmenger syndrome

Protocol summary

Summary

The purpose of this study is to determine the effect of intrapulmonary injection of stem cells on pulmonary artery pressure of patients with Eisenmenger syndrome whose heart defect has been repaired. This pilot study will be done on patients with previous ventricular septal defect and pulmonary hypertension who have undergone open heart surgery and have received routine medications for at least two years after surgery, but their pulmonary pressure hasn't decreased due to Eisenmenger syndrome. (about 5 patients) In this study right side catheterism will be done for patients and pulmonary artery pressure, pulmonary vascular resistance and right ventricle output will be recorded. Then mononuclear cells derived from culture of bone marrow aspirated specimen will be injected in right and left lungs in equal amounts. After procedure patients will be on their previous routine medications. They will be evaluated one, three, and six months after procedure. Echocardiography and six minutes walking test will be done and patients' functional class will be checked before procedure and in follow up after that. At the end of six months, right catheterism will be done for them again and pulmonary artery pressure, pulmonary vascular resistance and right ventricle output will be recorded. Data obtained before and after the procedure will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080435442N1**
Registration date: **2017-10-03, 1396/07/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-03, 1396/07/11

Registrant information

Name

Pegah Banafi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial to evaluate the effects of intrapulmonary injection of bone marrow derived mononuclear cells along with pulmonary hypertension drugs on pulmonary pressure in patients with Eisenmenger syndrome

Public title

Effect of intrapulmonary injection of stem cells in patients with pulmonary hypertension due to congenital heart defect whose heart disease has been repaired

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: operated VSD (ventricular septal defect) and pulmonary hypertension (Eisenmenger); not improved pulmonary HTN 2years after surgery (despite receiving routine medical therapy) Exclusion criteria: absence of consent; finding clot in heart; not tolerating catheterism

Age

No age limit

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 Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences Managing Building, Zand Street, Shiraz, Iran

City

Shiraz

Postal code

Approval date

2016-07-31, 1395/05/10

Ethics committee reference number

IR.SUMS.REC.1395.81

Health conditions studied

1

Description of health condition studied

Eisenmenger's syndrome

ICD-10 code

Q21.8

ICD-10 code description

other congenital malformation of cardiac septa

Primary outcomes

1

Description

pulmonary artery pressure

Timepoint

before intervention and 1month-3months-6months after procedure

Method of measurement

catheterism and echocardiography

2

Description

Pulmonary vascular resistance

Timepoint

before intervention and 1month-3months-6months after procedure

Method of measurement

catheterism and echocardiography

Secondary outcomes

1

Description

Right side cardiac output

Timepoint

Before intervention and 1month-3months-6months after the procedure

Method of measurement

echocardiography and catheterism

2

Description

patients' functional class

Timepoint

Before intervention and 1month-3months-6months after the procedure

Method of measurement

echocardiography and ECG and 6minutes walking test

3

Description

Results of 6 minute walking test

Timepoint

Before intervention and 1month-3months-6months after the procedure

Method of measurement

6 minute walking test

Intervention groups

1

Description

Bone marrow will be aspirated and cultured. Mononuclear cells will be derived. Cell extraction is based on ficoll based gradient method. The injectable sample is a cell suspension containing at least 20 million cells in 10 ml of physiologic serum as a cell carrier. The cell sample immediately after preparation (3-4 hours) is sent to the operating room in a sterile syringe with keeping the cold chain. Then these autologous mononuclear cells will be injected in both side pulmonary arteries by catheterism. The study has no control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emamreza clinic

Full name of responsible person

Dr.Hamid Amoozgar

Street address

third floor, Emamreza Clinic, Namazee square, Shiraz, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammadali Sahmeddini

Street address

Vice chancellor for research, 7th floor, Managing Building of Shiraz University of Medical Sciences, Zand street, Shiraz, Iran

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Hamid Amoozgar

Position

Professor of Pediatric cardiology

Other areas of specialty/work

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Dr.Hamid Amoozgar

Position

Professor of Pediatric cardiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty