

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of mid-term results of pulmonary valve reconstruction using right atrial appendage among children with tetralogy of Fallot

Protocol summary

Study aim

Making a pulmonary valve from the autologous right atrial appendage of the patients with tetralogy of Fallot and implanting this valve instead of the patient's own pulmonary valve

Design

In this clinical trial with a control group, for 20 patients, a pulmonary valve is made using the autologous right atrial appendage and compared with 20 patients with a trans-pulmonary annular patch method.

Settings and conduct

Following tetralogy of Fallot surgery, pulmonary valve insufficiency may be severe, and after a while a new pulmonary valve may need to be implanted. The new valve will become stenotic and insufficient and will need to be replaced. A new valve can be made in Shiraz, which is made of the autologous right atrial appendage with no fixative such as formaldehyde. If this new valve survives and grows as the patient grows, there is a possibility of no valve failure and stenosis, and therefore right ventricular failure is reduced and the possibility of the need for pulmonary valve implantation in the coming years is reduced. To prepare this valve, the appendage is first cut and stored in saline solution, then closed with sutures. The connecting muscle strips inside the RAA are cut to separate the two layers. All the larger muscle strips are carefully cut to make the layers thinner and more flexible. The valve is then inserted into the RVOT. These patients are compared with patients who have undergone transannular patch surgery by echocardiography and ECG every 6 months.

Participants/Inclusion and exclusion criteria

study participants are children with tetralogy of Fallot. Inclusion criteria include tetralogy of Fallot patients who have not previously had heart surgery and do not have a conduction disorder.

Intervention groups

Children with the impression of tetralogy of Fallot

Main outcome variables

Neo pulmonary valve regurgitation
Neo pulmonary valve stenosis
Conduction disturbances

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161220031496N2**

Registration date: **2022-04-14, 1401/01/25**

Registration timing: **prospective**

Last update: **2022-04-14, 1401/01/25**

Update count: **0**

Registration date

2022-04-14, 1401/01/25

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty
Scientific title
Evaluation of mid-term results of pulmonary valve reconstruction using right atrial appendage among children with tetralogy of Fallot

Public title
Evaluation of right atrial appendage valve in TOF
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Fallot tetralogy patients whose pulmonary valve needs to be repaired Fallot tetralogy patients who need insertion of a conduit Fallot tetralogy patients who need a transannular patch
Exclusion criteria:
Patients with small right atrial appendage Patients who have previously had heart surgery Patient with conduction anomalies

Age
From **6 months** old to **2 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Shiraz University of Medical Sciences
Street address
Zand Blvd
City
Shiraz
Province
Fars

Postal code
7134814336
Approval date
2022-04-06, 1401/01/17
Ethics committee reference number
IR.SUMS.MED.REC.1401.006

Health conditions studied

1
Description of health condition studied
Tetralogy Fallot
ICD-10 code
Q21.3
ICD-10 code description
Tetralogy of Fallot

2
Description of health condition studied
Pulmonary valve regurgitation
ICD-10 code
I37.2
ICD-10 code description
Nonrheumatic pulmonary valve stenosis with insufficiency

3
Description of health condition studied
Pulmonary valve stenosis
ICD-10 code
I37.2
ICD-10 code description
Nonrheumatic pulmonary valve stenosis with insufficiency

Primary outcomes

1
Description
Neo pulmonary valve stenosis
Timepoint
Q 6 months
Method of measurement
Transthoracic Echocardiography

2
Description
Neo pulmonary valve stenosis
Timepoint
Q 6 months
Method of measurement
Transthoracic echocardiography

3
Description
Possibility of conduction disturbances

Timepoint

Q 6 months

Method of measurement

ECG

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For the first time the pulmonary valve repair in children with tetralogy of Fallot, we make an autologous valve for the patients and it is assumed that this valve grows with age and does not suffer from stenosis and insufficiency, and this surgical method improves patients' lives. We hope that in this study we will obtain acceptable results from the function of this new valve as a pulmonary valve. This valve is made of the patient's right atrium at the time of surgery. And the possibility of new pulmonary valve insufficiency and stenosis may decrease, and therefore right ventricular failure in these patients decreases, and the possibility of the need for pulmonary valve implantation in the coming years for these patients also decreases. The appendage is clamped and is cut over the clamp and kept in a saline solution. The right atrial stamp is closed by suturing in two layers, first a mattress row under the vascular clamp and then an over-and-over suture run after removing the clamp. All the larger muscle bands are accurately excised to make the layers thinner and more pliable. The smaller muscle tissues are left in place to prevent accidental perforation of the cusps. The valve is now placed instead of the pulmonary valve, with the proximal end positioned at the annulus level and the distal end toward the pulmonary artery bifurcation. In cases with very short main pulmonary arteries, care should be taken not to obstruct the orifice of the right pulmonary artery by our valve tissue. 20 patients will be operated with this method.

Category

Treatment - Surgery

2**Description**

Control group: Children with tetralogy of Fallot who correspond to the intervention group in different conditions and we will operate on them with the conventional pulmonary transannular patch method, will be studied as this group. In this surgical procedure that has been done in the world for years, we make an incision in the right ventricular outflow tract towards the pulmonary valve, which continues to the pulmonary artery. The gap is then covered with a pericardial patch. Therefore, the pulmonary valve loses its activity in this method and the patient suffers from pulmonary valve insufficiency. 20 patients will be operated with this conventional method.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faghihi teaching Hospital

Full name of responsible person

Ahmadali Amirghofran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammadreza Edraki

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The surgical procedure as well as all the echocardiographic and ECG data will be provided in detail.

When the data will become available and for how long

unlimited

To whom data/document is available

All cardiac surgeons and cardiologists in the world

Under which criteria data/document could be used

To improve the surgery of tetralogy of Fallot

From where data/document is obtainable

Apply by email to the scientific or general manager of this project

What processes are involved for a request to access data/document

After a written request by email from the applicants, it will be provided to them by the scientific manager

Comments