Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Mohammad Reza Edraki

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 transnnular 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
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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