

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparative study of cardiac muscle damage markers and clinical outcomes in patients undergoing pulmonary valvular surgery using a cardiopulmonary bypass device using two beating heart pump and non-beating heart pump methods

Protocol summary

Study aim

Comparative study of cardiac muscle damage markers and clinical outcomes in patients undergoing pulmonary valvular surgery using a cardiopulmonary bypass device using two beating heart pump and non-beating heart pump methods

Design

We divided patients with functional dysfunction of pulmonary valves into pulmonary and pulmonary neoplasms and then examined the clinical outcomes and cardiac markers.

Settings and conduct

Tehran Shahid Rajaei Heart Hospital

Participants/Inclusion and exclusion criteria

Patients candidated for open heart surgery with primary or secondary pulmonary valve problems; the presence of ventricular and atrioventricular defects and the residual ventricular duct; cardiac and respiratory arrest during surgery

Intervention groups

Patients with pulmonary valvular dysfunction are undergoing open heart surgery, which are compared in both beating and non-beating heart pump methods.

Main outcome variables

Ejection Fraction(EF) Troponine(CTNI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180522039788N1**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **retrospective**

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

Sadegh Miraki

Name of organization / entity

Rajaei Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 4444

Email address

S_miraki@Rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-05-25, 1397/03/04

Actual recruitment start date

2018-01-05, 1396/10/15

Actual recruitment end date

2018-05-25, 1397/03/04

Trial completion date

empty

Scientific title

Comparative study of cardiac muscle damage markers and clinical outcomes in patients undergoing pulmonary valvular surgery using a cardiopulmonary bypass device using two beating heart pump and non-beating heart pump methods

Public title

Comparative study of cardiac muscle damage markers and clinical outcomes in patients undergoing pulmonary valvular surgery using a cardiopulmonary bypass device using two beating heart pump and non-beating heart pump methods

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients candidated for open heart surgery with primary or secondary pulmonary valve problems Patients have no PFO or ASD problem

Exclusion criteria:

The presence of ventricular and atrioventricular defects and the residual ventricular duct Cardiac and respiratory arrest during surgery

Age

From 4 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Actual sample size reached: 43

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**

Rajae Heart Center Ethics Committee

Street address

Valiasr Ave.

City

Tehran

Province

Tehran

Postal code

1996911151

Approval date

2018-02-17, 1396/11/28

Ethics committee reference number

RHC.AC.IR.REC.1396.86

Health conditions studied**1****Description of health condition studied**

Comparison of patients undergoing pulmonary valvular heart surgery with pulsed, pulsating, and pulsed heart disease

ICD-10 code

I98.1*Card

ICD-10 code description

I98.1*Cardiovascular disorders in other infectious and parasitic diseases classified elsewhere

Primary outcomes**1****Description**

Ejection Fraction

Timepoint

Pre Operation Time

Method of measurement

Blood Test

Secondary outcomes

empty

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

Intervention group: We compared patients with pulmonary function dysfunction and should undergo open heart surgery in two pulsed and pulsated ways, and there was no specific intervention in the two groups.

Category

Treatment - Surgery

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

Shahid Rajae Heart Hospital

Full name of responsible person

Dr. Ali Sadeghpour Tabaei

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Rajae heart center, Valiasr ave.

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alisadeghpour@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajae Heart Center

Full name of responsible person

Dr. Ali sadeghpour Tabaei

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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

Rajae Heart Center

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

Rajae Heart Center

Full name of responsible person

Sadegh Miraki

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Cardiology

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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Print article

When the data will become available and for how long

6 month

To whom data/document is available

Medical students

Under which criteria data/document could be used

Print article

From where data/document is obtainable

my self

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

question

Comments