Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Rajaee 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)

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+98 21 2235 4444

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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
Rajaee 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 Rajaee Heart Hospital
Full name of responsible person
Dr. Ali Sadeghpuor Tabaei
Street address
Rajaee heart center, Valiasr ave.
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alisadeghpour@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rajaee 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
Rajaee 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
Rajaee 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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Email
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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