Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of safety and efficacy of CardiaMed heart valve prosthesis in a multicentral study on patients undergoing open heart valve surgery

Protocol summary

Study aim

Specific Aim 1: The evaluation of safety and efficacy of CardiaMed prosthetic valve in Iranian patients undergoing open heart valve surgery Specific Aim 2: To compare the outcomes of patients with CardiaMed valves with those of patients with other mechanical valves

Design

Patients who are candidate for open heart valve surgery will be evaluated. First, patients will be informed about the details and features of CardiaMed valve. Then, after giving information to the patients, they will be requested to give consent for the implementation of CardiaMed valve, otherwise they will be implemented other mechanical valves. The randomization will be based on stratified randomization so that either of centers will randomly enroll patients into the study groups. The stratification of sample size will be based on either of centers' surgery volume so that Rajaie will enroll 60 patents and two other centers will enroll rest of cases, 20 patients in each center.

Settings and conduct

All patients will be selected from 3 centers in Iran, including Rajaie hospital, Hazrat Rasoul Hospital of Tehran, and Dena hospital of Shiraz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients aged 16-65 years old 2) Candidate for mechanical valve replacement due to rheumatic heart valve disease 3) Isolated mitral valve replacement Exclusion criteria: 1) Patients undergoing re-do surgeries 2) Patients with left ventricular ejection fraction ≤35% 3) Concomitant coronary artery bypasses graft surgery 4) Concomitant other valve surgeries (i.e. valvular repair) 5) Patients suspicious for native valve endocarditis 6) Patients with contraindicated warfarin consumption

Intervention groups

CardiaMed valve prosthesis Other mechanical valve

Main outcome variables

Valvular function Bleeding Re-operation rates

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210413050952N1**
Registration date: **2021-04-28, 1400/02/08**
Registration timing: **prospective**

Last update: **2021-04-28, 1400/02/08**
Update count: **0**

Registration date

2021-04-28, 1400/02/08

Registrant information

Name

Gholamreza Omrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2135

Email address

omrani@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and efficacy of CardiaMed heart valve prosthesis in a multicentral study on patients undergoing open heart valve surgery

Public title

Evaluation of safety and efficacy of CardiaMed heart valve prosthesis in a multicentral study on patients undergoing open heart valve surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for mechanical valve replacement due to rheumatic heart valve disease Isolated mitral valve replacement

Exclusion criteria:

Patients undergoing re-do surgeries Patients with left ventricular ejection fraction ≤35% Concomitant coronary artery bypasses graft surgery Concomitant other valve surgeries Patients suspicious for native valve endocarditis Patients with contraindicated warfarin consumption

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient selection will be performed based on inclusion and exclusion criteria. Each center will use simple randomization to enroll patients. The randomization will be based on stratified randomization so that either of centers will randomly enroll patients into study groups, including CardiaMed valve and St Jude valve. The stratification of sample size will be based on the centers' surgery volume so that Rajaie will enroll 60 patients and two other centers will enroll rest of cases, 20 patients in each center. The randomization method will be as simple randomization. All patients will be marked using a table of random numbers. The assignment of patients into three centers will be randomly done from number 0 to 100 so that 60, 20, and 20 patients will be randomly assigned into three centers, respectively. Then, each center will enroll assigned patients into two groups.

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

Rajaie Cardiovascular Medical and Research Center

Street address

No 1, Rajaie CMRC, Hashemi Rafsanjani Highway and Vali-e-Asr St. cross-section,

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2019-10-26, 1398/08/04

Ethics committee reference number

IR.RHC.REC.1400.001

Health conditions studied

1

Description of health condition studied

Rheumatic heart disease

ICD-10 code

I01

ICD-10 code description

Rheumatic fever with heart involvement

Primary outcomes

1

Description

Valvular function

Timepoint

Preoperative, Early postoperative, 6 months postoperative, 1 year postoperative

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Bleeding

Timepoint

Postoperative and 1 year after surgery

Method of measurement

Physical examination and checking INR

2

Description

Heart valve re-operation

Timepoint

Postoperative and 1 year after surgery

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: CardiaMed mechanical valve - In this group a CardiaMed mechanical valve (CardiaMed; Penza, Russia) will be implemented via an open heart surgery in the mitral valve position. During a general anesthesia, the rheumatic mitral valve will be excised during open surgery and the CardiaMed mechanical valve will be implanted instead.

Category

Treatment - Surgery

2

Description

Control group: St Jude mechanical valve - In this group a St Jude mechanical valve (St. Jude Medical, Inc., St. Paul, Minn) will be implemented via an open heart surgery in the mitral valve position. During a general anesthesia, the rheumatic mitral valve will be excised during open surgery and the St Jude mechanical valve will be implanted instead.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Gholamreza Omrani

Street address

No 1, Rajaie CMRC, Hashemi Rafsanjani Highway and Vali-e-Asr St. cross-sections

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2

Recruitment center

Name of recruitment center

Dena Hospital

Full name of responsible person

Ahmad Ali Amir Ghofran

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3

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dastavard-e-Sina Co.

Full name of responsible person

Mohammad Samiani

Street address

No52, Darya Blvd , Sa'adat Abad , Tehran

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Email
info@dastavardesina.com
Web page address
https://www.dastavardesina.com/

Grant name

Grant code / Reference number

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

Title of funding source
Dastavard-e-Sina Co.

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Gholamreza Omrani
Position
Assoc. Prof
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
After making data anonymous, it can be shared.
When the data will become available and for how long
At least, one year after study publication
To whom data/document is available
With researchers in the similar field via corresponding author after obtaining permission from ethics committee of main study center
Under which criteria data/document could be used
Only for meta-analysis studies
From where data/document is obtainable
Contact with corresponding author
What processes are involved for a request to access data/document
Contact with corresponding author and after obtaining permission from ethics committee of main study center
Comments
None