

# 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  $\leq 35\%$  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  $\leq 35\%$  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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info@rhc.ac.ir

##### Web page address

<http://rhc.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Dena Hospital

##### Full name of responsible person

Ahmad Ali Amir Ghofran

##### Street address

No1, Bolvar-e-Sattar Khan, Shiraz

##### City

Shiraz

##### Province

Fars

##### Postal code

71955967

##### Phone

+98 71 3649 0411

##### Fax

+98 71 3649 0433

##### Email

info@denahospital.com

##### Web page address

<http://www.denahospital.com/>

### 3

#### Recruitment center

##### Name of recruitment center

Hazrate Rasool Akram Medical Center

##### Full name of responsible person

Sam Zeraatian Nejad

##### Street address

No 1, Niayesh St, Sattar Khan st, Tehran

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##### Postal code

1445613131

##### Phone

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##### Fax

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##### Email

hrmc@iums.ac.ir

##### Web page address

<https://hrmc.iums.ac.ir/>

## 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

##### City

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##### Province

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**Postal code**

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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**

Cardiology

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Vali-e-Asr St. cross-sections**City**

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**Web page address**<http://rhc.ac.ir/>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

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**Web page address**<http://rhc.ac.ir/>**Person responsible for updating data****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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**Fax****Email**

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**Web page address**<http://rhc.ac.ir/>

## 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