

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of a new device for measuring the length of neochordae in mitral mitral valve repair based on perioperative echocardiographic views

#### Protocol summary

##### Summary

Mitral prolapse is a common cardiac disease whose patients are at higher risk for serious complications. Mitral valve (MV) repair offers several important advantages compared with valve replacement and it achieves excellent midterm and long-term results. Two major problems of using premeasured polytetrafluoroethylene (PTFE) neochordae (the loop technique) are deciding the length of the neochordae and tying the knot at the intended length. Therefore, a great need still exists to find new method to simplify and precise the length of neochordae. 20 patients with mitral valve prolaps who undergo mitral valve repair using neochorda will be recruited in this study. Trans thoracic echocardiography (TTE) will be done preoperatively for all patients. Two, three, and four chamber view of each patient will be preoperatively recorded with trans thoracic echocardiography (TTE). The device will be set with extracted measurements. Artificial corda loops are made using CV-5 of ePTFE sutures. After artificial chordae replacement, the ring annuloplasty will be done. Follow up: A leakage test after attaching the 1st loop; Post operative trans esophageal echocardiography (TEE) and determining the severity of mitral regurgitation (Wall motion Score Index (WMSI), MRSV, MAA, LVEF, ESV, EDV, Iso Volumic Relaxation Time (IVRT), (IVRT/(QE-QE^' ) , (Chamber Relaxation velocity)/(Myocard relaxation velocity) (E/E^' ) , HR); TEE 3 months after discharge; CBT time; Intubation period in ICU.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201207218860N4**

Registration date: **2012-08-11, 1391/05/21**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-08-11, 1391/05/21

##### Registrant information

###### Name

Alireza Alizadeh Ghavidel

###### Name of organization / entity

Rajaei Heart Center

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2392 2147

###### Email address

aghavidel@rhc.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Rajaei Heart Center

##### Expected recruitment start date

2012-07-22, 1391/05/01

##### Expected recruitment end date

2013-07-23, 1392/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of a new device for measuring the length of neochordae in mitral mitral valve repair based on perioperative echocardiographic views

##### Public title

A new device for measuring the length of neochordae in mitral mitral valve repair based on perioperative echocardiographic views

## Purpose

Diagnostic

## Inclusion/Exclusion criteria

Inclusion criteria: Patients with Mitral prolaps who undergo mitral valve repair using neochorda.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 20

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Junction of Shahid Hemmat and Shahid Chamran expressways

##### City

Tehran

##### Postal code

#### Approval date

2012-07-15, 1391/04/25

#### Ethics committee reference number

91-01-149-17122-59685

## Health conditions studied

### 1

#### Description of health condition studied

Mitral Valve Disease

#### ICD-10 code

I34.1

#### ICD-10 code description

Floppy mitral valve syndrome

## Primary outcomes

### 1

#### Description

Mitral Valve prolaps measurement after using neochordae

#### Timepoint

After operation, 3 months after release

#### Method of measurement

Transesophageal echocardiography

## Secondary outcomes

### 1

#### Description

Cardiopulmonary bypass time

#### Timepoint

During operation

#### Method of measurement

Timer

### 2

#### Description

Duration of intubation at ICU

#### Timepoint

ICU stay

#### Method of measurement

Timer

## Intervention groups

### 1

#### Description

There is just treatment group in this study. Transthoracic echocardiography is performed in all patients. The coordinates of papillary muscle tips and mitral valve leaflets is measured from echocardiography. The new device is set and the neochordae become ready for mitral valve repair. The operation is finished after annuloplasty.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rajaei Heart Center

##### Full name of responsible person

Dr. Alireza Alizadeh Ghavidel

##### Street address

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Rajaei Heart Center

**Full name of responsible person**

Dr.Majid Haghjoo

**Street address**

Valiasr Ave. Nyayesh Blvd.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Rajaei Heart Center

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Rajaei Heart Center

**Full name of responsible person**

Dr. Alireza Alizadeh Ghavidel

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

Valiasr Ave, Nyayesh Blvd.

**City**

Tehran

**Postal code**

**Phone**

+98 21 2392 2147

**Fax**

**Email**

aghavidel@rhc.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Rajaei Heart Center

**Full name of responsible person**

Dr. Alireza Alizadeh Ghavidel

**Position**

Assistant Professor of cardiac surgery

**Other areas of specialty/work**

**Street address**

Valiasr Ave, Nyayesh Blvd.

**City**

Tehran

**Postal code**

**Phone**

+98 21 2392 2147

**Fax**

**Email**

aghavidel@rhc.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Rajaei Heart Center

**Full name of responsible person**

Dr. Alireza Alizadeh Ghavidel

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Valiasr Ave, Nyayesh Blvd.

**City**

Tehran

**Postal code**

**Phone**

**Fax**

**Email**

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*