

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 measurment 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

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Contact

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Position

Assistant Professor of cardiac surgery

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Position

Assistant Professor

Other areas of specialty/work

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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