Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 annuluplasty 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
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Iran (Islamic Republic of)
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rajaei Heart Center
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Valiasr Ave. Nyayesh Blvd.
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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
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

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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