Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of sildenafil effects and placebo on mortality and morbidity in patients with severe mitral stenosis and reactive pulmonary hypertension after mitral valve replacement

Protocol summary

Summary

Pulmonary hypertension is an important prognostic factor for mortality and morbidity in patients with severe mitral stenosis. To the best of our knowledge, there is not specific and effective treatment for these patients. So we will use sildenafil 25 milligrams three times a day, from 3 days before to 6 weeks after mitral valve replacement surgery, in randomized pattern. For evaluation of sildenafil effects, we will compare pulmonary artery pressure and left ventricular function and mortality rate, before and 6 weeks after operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072818625N1**
Registration date: **2014-09-09, 1393/06/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-09, 1393/06/18

Registrant information

Name
Tahereh Davarpasand
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Tehran University of Medical Sciences/ Tehran Heart Center
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Recruitment status

Recruitment complete

Funding source

Tehran Heart Center

Expected recruitment start date

2014-09-06, 1393/06/15

Expected recruitment end date

2015-09-06, 1394/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sildenafil effects and placebo on mortality and morbidity in patients with severe mitral stenosis and reactive pulmonary hypertension after mitral valve replacement

Public title

prognostic effect of sildenafil in patients with severe mitral stenosis and reactive pulmonary hypertension candidate for mitral valve replacement at Tehran Heart Center

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with severe mitral stenosis; Pulmonary artery pressure more than 35 mm Hg in trans esophageal echocardiography; Reactive pulmonary hypertension according right heart catheterization (difference between mean pulmonary artery pressure and Pulmonary Capillary Wedge Pressure> 12mmhg)
Exclusion criteria: Necessity of nitrate; Significant hypotension after first dose of sildensfil; Mitral regurgitation more severe than moderate degree; Necessity of aortic or tricuspid valve replacement;

Concomitant Coronary artery bypasses graft surgery

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Trans esophageal echocardiography 3 days before and 6 weeks after surgery by one echocardiologist sildenafil 25 mg TDS from 3 days befor surgery until 6 weeks after surgery in randomized pattern

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences/Tehran Heart Center

Street address
North kargar Street

City
Tehran

Postal code
1411713138

Approval date
2013-09-13, 1392/06/22

Ethics committee reference number
675

Health conditions studied

1

Description of health condition studied
Reactive Pulmonary Hypertension

ICD-10 code
I27.8

ICD-10 code description
Other specified pulmonary heart diseases

2

Description of health condition studied
severe mitral stenosis

ICD-10 code
I05.0

ICD-10 code description
Mitral stenosis

Primary outcomes

1

Description
Pulmonary Artery Pressure

Timepoint
7 days before mitral valve replacement/ 6 week after mitral valve replacement

Method of measurement
Transthoracic Echocardiography

2

Description
Left Ventricular Ejection Fraction

Timepoint
7 days before mitral valve replacement/ 6 week after mitral valve replacement

Method of measurement
Transthoracic Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Patients with severe mitral stenosis and reactive pulmonary hypertension, who are candidate for elective mitral valve replacement using a 1: 1 method, are randomly divided into two groups: Group 1(intervention) patients will be administrated three days prior to surgery, oral sildenafil 25 mg three times a day. At firs postoperative day, Sildenafil Dosage will be increased to 50 mg three times a day.

Category
Treatment - Drugs

2

Description
Second (control) group will receive placebo during study period.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran Heart Center
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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
Tehran 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