

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 Davarpassand

Name of organization / entity

Tehran University of Medical Sciences/ Tehran Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 88029600

Email address

davarpassand@sina.tums.ac.ir

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 sildenafil; 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 before 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 first 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

Tahereh Davarpassand

Street address

North Kargar Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Heart Center

Full name of responsible person

Tahereh Davarpassand

Street address

North Kargar Street

City

Tehran

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

Contact

Name of organization / entity

Tehran Heart Center

Full name of responsible person

Tahereh davarpassand

Position

Cardiologist

Other areas of specialty/work**Street address**

North Kargar Street

City

Tehran

Postal code

1411713138

Phone

+98 21 8802 9600

Fax

+98 21 8802 9256

Email

tahereh.davarpassand@yahoo.com;

davarpassand@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran Heart center

Full name of responsible person

Tahereh davarpassand

Position

Cardiologist

Other areas of specialty/work**Street address**

North Kargar Street

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Fax

+98 21 8802 9256

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davarpassand@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran Heart Center

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davarpassand@sina.tums.ac.ir

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