

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of pulmonary artery pressure in response to activity in patients with non severe mitral valve stenosis after commissurotomy and its relationship with some echocardiographic variables

Protocol summary

Study aim

Evaluation of pulmonary artery systolic pressure and other echocardiographic variables at rest Evaluation of pulmonary artery systolic pressure and other echocardiographic variables after exercise stress test

Design

Non randomised Clinical trail with single group of 200 patiens starts on April 2018 and is followed for 6 months.

Settings and conduct

Patiens reffered to Madani heart center clinic with inclusion criteria undergo echocardiography with messurment of varables then undergo stress exersice test with Bruce protocol. After the test, Pulmonary artery systolic pressue is measured again with echo and data is analysed

Participants/Inclusion and exclusion criteria

Patients with history of mitral valve commissurotomy and non severe stenosis with normal pulmonary, hepatic and renal function and satisfaction for taking part in this study

Intervention groups

Patients go under 6 minute stress exercise test with Bruce protocol after first echocardiography and after the test, pulmonary artery systolic pressure is measured again with echocardiography

Main outcome variables

Pumonary artery systolic pressue increase above 60 mmHg after execise is indication of intervention with commissurotomy for mitral stenosis of these patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211001052645N1**

Registration date: **2022-01-23, 1400/11/03**

Registration timing: **retrospective**

Last update: **2022-01-23, 1400/11/03**

Update count: **0**

Registration date

2022-01-23, 1400/11/03

Registrant information

Name

Naser Aslanabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 7767

Email address

aslanabadin@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

2018-04-19, 1397/01/30

Actual recruitment end date

2018-10-22, 1397/07/30

Trial completion date

2019-02-19, 1397/11/30

Scientific title

Evaluation of pulmonary artery pressure in response to activity in patients with non severe mitral valve stenosis after commissurotomy and its relationship with some echocardiographic variables

Public title

Evaluation of pulmonary artery pressure in response to activity in patients with non severe mitral valve stenosis after commissurotomy and its relationship with some echocardiographic variables

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with history of mitral valve commissurotomy and non severe mitral stenosis Normal pulmonary,hepatic and renal function patients satisfaction to take part in study

Exclusion criteria:

Pulmonary artery systolic pressure above 60 mmHg at rest Disability for exercise test Restrictive diseases like coronary artery disease,lung disease,... Severe Mitral valve stenosis or regurgitation Patients discontent for study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Actual sample size reached: **200**

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

Tabriz university of Medical science

Street address

Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-09-17, 1397/06/26

Ethics committee reference number

IR.TBZMED.REC.1397.513

Health conditions studied

1

Description of health condition studied

Patients with non severe or progressive mitral valve stenosis and history of commissurotomy

ICD-10 code

I05.0

ICD-10 code description

Rheumatic mitral stenosis

2

Description of health condition studied

Increased pulmonary artery systolic pressure after exercise

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pulmonary artery systolic pressure above 60mmHg after exercise

Timepoint

Messurement of Pulmonary artery systolic pressure before exercise test and immediately after that

Method of measurement

Echocardiography machine

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with history of mitral valve commissurotomy and non severe mitral valve stenosis admitted to clinic

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Manai Heart center

Full name of responsible person

Nase Aslanabadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person

Naser Aslanabadi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all the data could be published

When the data will become available and for how long

Data would be available 6 months after edition

To whom data/document is available

The researchers and industrial occupiers could access the data

Under which criteria data/document could be used

Data of this study could be used with saving the privacy of patients

From where data/document is obtainable

Call:09141013328_09143110844

What processes are involved for a request to access data/document

The Researchers could reach the data after 1 moth evaluation

Comments