

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Assessing the effect of fluoxetine on the clinical symptoms and echocardiographic findings in patients with mitral valve prolapse and generalized anxiety disorder, referred to Mashhad outpatient cardiology clinics in 2015.

#### Protocol summary

2015-01-31, 1393/11/11

##### Summary

Evaluation of fluoxetine effect on clinical symptoms and echocardiographic findings in patients with mitral valve prolapse and generalized anxiety disorder is the aim of this study. Patients who their mitral valve prolapse is confirmed by echocardiography and have clinical symptoms of generalized anxiety disorder will fill a validated Persian version of GAD-7 questionnaire and enter the study. Medical illnesses which directly or indirectly can induce anxiety or patients who are taking any drugs which can affect generalized anxiety disorder will be excluding. According to the study sample size which is calculated as 60 participants, patients will be randomly categorized in to two groups. Each group will take their medication for 8 weeks. First group will take 10mg of propranolol three times a day and the second group will take same dose of propranolol plus 10mg fluoxetine daily. Each two weeks, the patients will be evaluated for exclusion criteria by physicians and each week patients will document their symptoms according to the 11 question likert scale. After 8 weeks of study period, each patient will undergo echocardiography and the results will be documented in their questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014102819721N1**  
Registration date: **2015-01-31, 1393/11/11**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Reza Jafarzadeh Esfehani

###### Name of organization / entity

Sabzevar University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3843 3015

###### Email address

jafarzadehr911@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Sabzevar University of Medical Science

##### Expected recruitment start date

2015-03-17, 1393/12/26

##### Expected recruitment end date

2015-07-20, 1394/04/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing the effect of fluoxetine on the clinical symptoms and echocardiographic findings in patients with mitral valve prolapse and generalized anxiety disorder, referred to Mashhad outpatient cardiology clinics in 2015.

##### Public title

Effect of fluoxetine on clinical symptoms and

echocardiographic findings in patients with mitral valve prolapse and generalized anxiety disorder.

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: patients who their mitral valve prolapse (MVP) is confirmed by echocardiography and have clinical symptoms of MVP (at least must have palpitation or chest pain). Exclusion criteria: medical conditions which directly or indirectly can induce anxiety including anemia; hypercalcemia; hypoglycemia; drugs or alcohol withdrawal syndrome; vertigo; thyrotoxicosis; hypercapnea; hyponatremia; central nervous system disorders such as seizures; asthma; ischemic heart disease; malignancies; drugs such as anticonvulsants; antimicrobials; bronchodilators; digitalis; estrogen; insulin; nonsteroidal anti-inflammatory drugs; antidepressants; antihistamines; calcium channel blockers; dopamine; inotropics; levodopa; thyroxine; corticosteroids; smoking; patients who don't fully fill DSM-IV criteria and are not included in generalized anxiety disorder category; any other documented psychological problems; patients who are not interested in continuing medications and are willing to be excluded; patients who do not take their medications regularly; patients who are prescribed with other drugs during the study; patients who are not capable to continue study because of drug adverse effects or need to change their drugs according to physicians order.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

## Name of ethics committee

Sabzevar University of medical science research and technology department

## Street address

Medicine Faculty - building No.2 - 5th kilometer of Tehran road - Sabzevar - Iran

## City

Sabzevar

## Postal code

## Approval date

2014-08-04, 1393/05/13

## Ethics committee reference number

3/33/ ک پ ژ

## Health conditions studied

### 1

#### Description of health condition studied

Generalized anxiety disorder

#### ICD-10 code

F41.1

#### ICD-10 code description

Generalized anxiety disorder

### 2

#### Description of health condition studied

mitral valve prolapse

#### ICD-10 code

I34.1

#### ICD-10 code description

Mitral (valve) prolapse

## Primary outcomes

### 1

#### Description

Pain severity

#### Timepoint

Every week

#### Method of measurement

Base on 11 point likert scale

### 2

#### Description

Echocardiographic changes

#### Timepoint

At the beginning and the end of study

#### Method of measurement

By use of transthoracic echocardiography

### 3

#### Description

Palpitation

#### Timepoint

Every week

#### Method of measurement

Base on 11 point likert scale

## Secondary outcomes

### 1

#### **Description**

Drugs adverse effects

#### **Timepoint**

Any point in the study period

#### **Method of measurement**

Physician will ask participants about drug adverse reactions in each visit and also the participants will be educated to report any cardio-respiratory or mood changes during the study.

### 2

#### **Description**

Onset of new disease

#### **Timepoint**

Any point in the study period

#### **Method of measurement**

Participants will call the physician any time they get new illnesses which is mentioned in exclusion criteria of the study

### 3

#### **Description**

Start using new drugs

#### **Timepoint**

Any point in the study period

#### **Method of measurement**

Participants will call their physician any time they start new drugs

### 4

#### **Description**

Generalized anxiety disorder become worsen

#### **Timepoint**

Every two weeks or any time in the study

#### **Method of measurement**

Every participants mood will be evaluated in each visit and also the participants will call their physician any time they fill their mood is becoming worsen

### 5

#### **Description**

Worsening of cardiac condition

#### **Timepoint**

Every two week or any time in the study

#### **Method of measurement**

In each visit the physician will evaluate the participants cardiac condition and the patients will be educated to immediately report any changes in their conditions or any alarm signs

### 6

#### **Description**

Irregular drug use

#### **Timepoint**

Every two weeks

#### **Method of measurement**

Patients will be asked about using their medications

### 7

#### **Description**

Failure in continuing the study

#### **Timepoint**

Any point in the study period

#### **Method of measurement**

Personal willing to change their drugs or exiting the study because of taking long trips or personal willing

## Intervention groups

### 1

#### **Description**

Propranolol 10mg three times a day for eight weeks

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Propranolol 10mg three times a day and Fluoxetine 10mg once daily for eight weeks

#### **Category**

Treatment - Drugs

## Recruitment centers

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Emam Reza Educational, Research and Treatment Center Clinics

##### **Full name of responsible person**

Majid Jalalyazdi

##### **Street address**

##### **City**

Mashhad

## Sponsors / Funding sources

### 1

#### **Sponsor**

##### **Name of organization / entity**

Sabzevar University of Medical Science

##### **Full name of responsible person**

Mohammad Mohammad-Zadeh (Vice Chancellor for Research)

##### **Street address**

Department of research and technology - Sabzevar University of Medical Science - building No.1 - 5th kilometer of Tehran road - Sabzevar - Iran

##### **City**

Sabzevar

##### **Grant name**

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Sabzevar University of Medical Science

**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**

Mashhad University of Medical Science

**Full name of responsible person**

Majid Jalalyazdi

**Position**

Cardiologist

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

Edalatian emergency department, Imam Reza Hospital, Mashhad, Iran

**City**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Science

**Full name of responsible person**

Majid Jalalyazdi

**Position**

Cardiologist

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

Edalatian emergency department, Imam Reza Hospital, Mashhad, Iran

**City**

Mashhad

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jalalyazdi@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Sabzevar University of Medical Science

**Full name of responsible person**

Reza Jafarzadeh Esfehani

**Position**

Medical Student

**Other areas of specialty/work****Street address****City****Postal code****Phone**

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**Fax****Email**

drrezajafarzadeh@yahoo.com

**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*