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

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

2015-01-31, 1393/11/11

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;hypercalemia;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;broncho dilators;digitalis;estrogen;insulin;nonsteroidal anti-inflammatory drugs;antidepressants;antihistamines;calcium channel blockers;dopamine;inotropics;levodopa;thyroxine;corticosteroids;smoking;patients who dont full 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/ژ پ ک

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 begining 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
Mashhad
Postal code
Phone
+98 51 3854 3031
Fax
Email
jalalyazdi@yahoo.com
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
Postal code
Phone
+98 51 3854 3031
Fax
Email
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
00
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