Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Study of the therapeutic effects of Atomoxetine in comparison with placebo on reducing the incidence of symptoms in patients with recurrent vasovagal syncope;

Protocol summary

Study aim
Study of therapeutic effects of Atomoxtein in reducing the incidence of symptoms in patients with recurrent vasovagal syncope

Design
This study is a double-blind placebo-controlled randomized clinical trial.

Settings and conduct
In this study, patients will be recruited from referrals to the specialized syncope clinic of Tehran Heart Center. Eligible participants will be randomized to 2 parallel groups with a 1:1 ratio: 1) Standard treatment plus atomoxetine. 2) Standard treatment plus identical-looking placebo. Medications will be given to patients in sequentially numbered opaque sealed envelopes. This is a double-blind randomized clinical trial in which the patients and the investigators will be blinded to the randomized intervention. Follow-up visits will be done on month 1 and 3.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who come to the Tehran Heart Center with a complaint of syncope or pre-syncope with the clinical diagnosis of vasovagal syncope or have undergone tilt test, if needed, and experienced at least 3 syncopal episodes in the past 3 months. Exclusion criteria: Age under 10 or over 70 years old History of uncontrolled blood pressure History of structural heart disease History of epilepsy History of closed angle glaucoma History of diabetes mellitus History of coronary artery disease Ejection fraction < 50% Use of monoamine oxidase inhibitors (MAOIs) Use of selective serotonin reuptake inhibitors (SSRIs) Use of anticonvulsants

Intervention groups
Intervention group: Administration of Atomoxetine with a dose of 20 mg per day for 2 weeks and 40 mg per day for another 2 weeks if tolerated Control group: Receive placebo with the above command

Main outcome variables
The number of (pre-)syncopal episodes on month 1 and 3.

General information

Reason for update
Completion and modification of the protocol of the study according to the setting of the recruitment

Acronym

IRCT registration information
IRCT registration number: **IRCT20180125038507N1**
Registration date: **2018-08-03, 1397/05/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-24, 1398/10/03**
Update count: **1**

Registration date
2018-08-03, 1397/05/12

Registrant information

Name
Masih Tajdini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8802 9640

Email address
mtajdini@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

2018-07-25, 1397/05/03

Actual recruitment end date

2019-07-23, 1398/05/01

Trial completion date

2019-10-23, 1398/08/01

Scientific title

Study of the therapeutic effects of Atomoxetine in comparison with placebo on reducing the incidence of symptoms in patients with recurrent vasovagal syncope;

Public title

Study of therapeutic effects of Atomoxtein in reducing the symptoms of patients with recurrent vasovagal syncope

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who come to the Tehran Heart Center with a complaint of syncope or pre-syncope with the clinical diagnosis of vasovagal syncope or have undergone tilt test, if needed, and experienced at least 3 syncopal episodes in the past 3 months.

Exclusion criteria:

Age under 10 or over 70 years old History of uncontrolled blood pressure History of structural heart disease History of epilepsy History of closed angle glaucoma History of diabetes mellitus History of coronary artery disease Ejection fraction < 50% Use of monoamine oxidase inhibitors (MAOIs) Use of selective serotonin reuptake inhibitors (SSRIs) Use of anticonvulsants

Age

From **10 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomized and divided into two groups based on permutation blocks and they fall into one of the medication and placebo groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. Both patients and investigators were blinded to the medication and placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine- Tehran University of Medical Sciences

Street address

North kargar street, Tehran heart center

City

Tehran

Province

Tehran

Postal code

1411713138

Approval date

2018-07-25, 1397/05/03

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.273

Health conditions studied

1

Description of health condition studied

Syncope

ICD-10 code

R55

ICD-10 code description

Syncope and collapse

Primary outcomes

1

Description

The number of (pre-)syncopal episodes

Timepoint

Follow-up visit at month 1 and 3

Method of measurement

Based on history and physical exam

Secondary outcomes

1

Description

Anxiety

Timepoint

Follow-up visit on month 3

Method of measurement

Hospital Anxiety and Depression Scale Questionnaire

2

Description
Depression
Timepoint
Follow-up visit on month 3
Method of measurement
Hospital Anxiety and Depression Scale Questionnaire

3

Description
Physical quality of life
Timepoint
Follow-up visit on month 3
Method of measurement
36-Item Short Form Survey Questionnaire

4

Description
Mental quality of life
Timepoint
Follow-up visit on month 3
Method of measurement
36-Item Short Form Survey Questionnaire

Intervention groups

1

Description
Intervention group: Atomoxetine 20 mg daily, taken orally, for 2 weeks and 40 mg daily for another 2 weeks, if tolerated. The pills will be sealed in 2 envelopes for each 2-week period: 14 pills (20 mg) in envelope A and 14 pills (40 mg) in envelope B.
Category
Treatment - Drugs

2

Description
Control group: Placebo pills are administered orally daily for a period of 4 weeks in envelopes A and B as discussed earlier. Placebos will be produced by the pharmacy department of Tehran University of Medical Sciences.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Masih Tajdini
Street address
North kargar stret
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Email
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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 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
Tehran University of Medical Sciences
Full name of responsible person
Masih Tajdini
Position
Assistant professor of cardiology
Latest degree
Specialist
Other areas of specialty/work

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Person responsible for scientific inquiries

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Ali Bozorgi
Position
Assistant professor of cardiology
Latest degree
Specialist
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 data will be published
When the data will become available and for how long
2019
To whom data/document is available
All
Under which criteria data/document could be used
All
From where data/document is obtainable
Dr Masih Tajdini
What processes are involved for a request to access data/document
Appointment
Comments