

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Rehabilitation for reducing the symptoms and improving the quality of life in patients with recurrent vasovagal syncope: a randomized clinical trial

Protocol summary

Study aim

Assessment of rehabilitation for recurrent syncope

Design

The study is a clinical trial with a control group, with parallel and randomized groups.

Settings and conduct

Patients referred to Tehran Heart Center Syncope Clinic are randomly divided into two groups for receiving 1) rehabilitation program 2) standard treatment. The intervention group is treated with the rehabilitation program and the control group receives standard treatment. Patients will be followed for syncope and presyncope symptoms, quality of life, anxiety and depression; at baseline, then at one month, three months, six months, and one year. The results are analyzed by SPSS software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients presenting with syncope to Tehran Heart Center who have been diagnosed with a tilt test or clinical diagnosis of vasovagal syncope and have experienced at least two attacks during the year.
Exclusion criteria: Patients presenting with structural heart diseases, abnormal ECG, cardiac arrhythmias, neurological diseases, and patients who are receiving psychiatric treatment. Pregnant or breastfeeding women

Intervention groups

Intervention group: The rehabilitation program which consists of three 4-hour sessions during the first month of the treatment: - Practice with inclined boards - Psychological counseling based on HADS criteria and referral to a psychiatrist if needed -Counterpulsation maneuvers and aerobic exercise and home tilt training
Control group: standard treatment including education on the nature of the disease, home tilt training, and Counterpulsation maneuvers

Main outcome variables

recurrence of syncope, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180125038507N2**

Registration date: **2020-01-15, 1398/10/25**

Registration timing: **retrospective**

Last update: **2020-01-15, 1398/10/25**

Update count: **0**

Registration date

2020-01-15, 1398/10/25

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

2019-05-22, 1398/03/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Rehabilitation for reducing the symptoms and improving the quality of life in patients with recurrent vasovagal syncope: a randomized clinical trial

Public title

Rehabilitation for lessening the symptoms and improving the quality of life in patients with repeated vasovagal syncope

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with 2 or more vasovagal syncope episodes during the last year

Exclusion criteria:

Patients with structural heart diseases
Patients with abnormal ECG
Patients with neurologic diseases
Pregnant or breastfeeding women
Patients who receive psychiatric medications

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomized and divided into two groups of standard care (education-based), and standard care plus rehabilitation, based on permutation blocks. We will have four eight-spot blocks and three six-spot blocks. Each block contains equal spots for standard care and rehabilitation groups.

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

Ethics committee of Tehran University of Medical Sciences

Street address

North Kargar Street, Tehran Heart Center, Tehran,

Iran

City

Tehran

Province

Tehran

Postal code

1411713138

Approval date

2019-10-10, 1398/07/18

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.573

Health conditions studied

1

Description of health condition studied

Vasovagal Syncope

ICD-10 code

R55

ICD-10 code description

Syncope and collapse

Primary outcomes

1

Description

Prevalence of syncope and syncope symptoms

Timepoint

baseline, one month, three months, six months, 12 months

Method of measurement

Direct observation and measurement

2

Description

Quality of life

Timepoint

baseline, one month, three months, six months, 12 months

Method of measurement

SF36 Scale

3

Description

anxiety and depression

Timepoint

baseline, one month, three months, six months, 12 months

Method of measurement

HADS Sclae

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The one-month rehabilitation program consists of three sessions of a four-hour program: exercise with tilt table, Psychological counseling based on HADS score and referring to a psychiatrist if necessary, Doing counterpulsation maneuvers and aerobic sports, and home tilt training

Category

Behavior

2

Description

Control group: Receiving Standard treatment program including education about the disease and counterpulsation maneuvers and home tilt training

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Masih Tajdini

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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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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

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

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General Practitioner

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All the data about our participants

When the data will become available and for how long

After the study

To whom data/document is available

All of readers

Under which criteria data/document could be used

All the situations

From where data/document is obtainable

Corresponding author

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

Just should be send by email

Comments