

# 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

##### Street address

Tehran Heart Center, North Kargar Street

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+98 21 8802 9600

##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Masih Tajdini

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##### City

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##### Province

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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 scientific inquiries

#### Contact

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Tehran University of Medical Sciences

##### Full name of responsible person

Masih Tajdini

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##### Latest degree

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##### Other areas of specialty/work

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Faezeh Aghajani

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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**Phone**

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**Fax**

**Email**

**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**