

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Feasibility, acceptability, safety and efficacy of transcutaneous auricular vagus nerve stimulation for reducing postoperative atrial fibrillation in patients undergoing coronary artery bypass graft surgery; A study protocol for a pilot randomized sham-controlled trial

Protocol summary

Study aim

Assessment of feasibility, acceptability, and safety of transcutaneous auricular vagus nerve stimulation for reducing post-CABG atrial fibrillation

Design

Randomized double-blind parallel-design sham-controlled pilot study of 20 participants. Randomisation will be performed at an external site.

Settings and conduct

This study will be conducted in Tehran Heart Center. After surgery, the intervention will be applied from day 0 to day 4 of the ICU admission, every day in two 40-minute sessions with a 20-minute break between the two sessions. Vital signs and possible complications after the intervention will be recorded. The patient will be subjected to 24-hour ECG holter monitoring on a daily basis. Finally, the degree of feasibility and acceptability will be evaluated by counting the amount of completed intervention and special questionnaires, respectively.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult subjects who are candidate for an elective CABG and have sinus rhythm at baseline.

Exclusion criteria: Patients with a documented history of AF; Hemodynamic instability; Severe heart failure; Chronic use of amiodarone; High-degree atrioventricular block; Recent stroke; Recurrent vasovagal syncope; the presence of a pacemaker or an ICD; Pregnancy; ear pain; recent ear trauma.

Intervention groups

Active intervention: Active ta-VNS will be performed with a clip attached to the tragus region at 20 hertz, 200 ms, 30 s off and 30s on, and at a current below the discomfort threshold for two separate sessions of 40-minute stimulation daily with 20-minute rest between them. Sham intervention: Sham ta-VNS will be performed with the same parameters and region as the active

group, but with the status set to sham, which means no current will be transformed.

Main outcome variables

Feasibility of the intervention and procedures;
Acceptability; Safety

General information

Reason for update

Acronym

TRAVAG-POAF

IRCT registration information

IRCT registration number: **IRCT20130707013886N2**

Registration date: **2022-11-12, 1401/08/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-12, 1401/08/21**

Update count: **0**

Registration date

2022-11-12, 1401/08/21

Registrant information

Name

Ali Vasheghani Farahani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-01, 1401/08/10

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Feasibility, acceptability, safety and efficacy of transcutaneous auricular vagus nerve stimulation for reducing postoperative atrial fibrillation in patients undergoing coronary artery bypass graft surgery; A study protocol for a pilot randomized sham-controlled trial

Public title

Vagus nerve stimulation for reducing postoperative atrial fibrillation

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult subjects who are candidate for an elective CABG

Age $\geq$ 18 Sinus rhythm at baseline ECG

Exclusion criteria:

Patients with a documented history of AF and other supraventricular arrhythmia Hemodynamic instability that required inotropic agents Severe congestive heart failure (New York Heart Association class III or IV)

Congenital heart disease Chronic use of amiodarone

High-degree atrioventricular block that required

temporary pacing Symptomatic sinus bradycardia or

sinus node dysfunction at baseline without an

implantable pacemaker Recent stroke within the past 6

months Recurrent vasovagal syncope Known

channelopathy such as Brugada syndrome, long QT

syndrome, or Catecholaminergic monomorphic

ventricular tachycardia The presence of a pacemaker or

an implanted cardioverter-defibrillator Pregnancy Facial

or ear pain, or recent ear trauma Unable or unwilling to

comply with protocol requirements

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done via permuted block technique. Randomization unit will be the blocks with

sizes of 2 and 4. Randomization tools in

"www.sealedenvelope.com" will be used for performing randomization. Researcher A is responsible for randomization and determine specific codes for each patients. Only those researchers (B and C) who are responsible for performing the intervention will be aware of allocation. Outcome assessors (D) will be blinded from allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant: In this study, stimulation causes a tingling sensation in the ear area. The participants are told that after the tingling sensation, this feeling may decrease or disappear altogether, which is due to the reduction of sensitivity of the skin of that area. In the active intervention group, this tingling does not change over time or becomes slightly less but does not disappear because it receives constant stimulation. But in the sham group, stimulation is first given for 1 minute (this amount does not produce a clinical effect) so that the patient does not have the mindset that he will not receive the stimulation, and then the stimulation is stopped.

Outcome assessor and data analyst: Outcome assessor collect the outcomes without talking to the patient and the researcher who performs the intervention and then send them to the researcher who is responsible for data management and analysis.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran Heart Center

Street address

Tehran Heart Center, North Karegar street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411713138

Approval date

2021-11-04, 1400/08/13

Ethics committee reference number

IR.TUMS.THC.REC.1400.051

Health conditions studied

1

Description of health condition studied

Postoperative atrial fibrillation

ICD-10 code

I48.0

ICD-10 code description

Paroxysmal atrial fibrillation

Primary outcomes

1

Description

Feasibility of the intervention

Timepoint

At the end of the study

Method of measurement

The amount of time (in minutes) of device use per day and Number of completed session

2

Description

Feasibility of the measurements and assessments procedures

Timepoint

At the end of the study

Method of measurement

The number of completed assessments

3

Description

Acceptability of the intervention

Timepoint

At the end of the study

Method of measurement

TAQ questionnaire

4

Description

Safety of the study

Timepoint

After intervention on a daily basis

Method of measurement

Physical examination

Secondary outcomes

1

Description

Occurrence of in-hospital POAF

Timepoint

Days 0 to 4 (or at discharge day, whichever is earlier)

Method of measurement

24-hour ECG holter monitoring

2

Description

Time to first POAF event

Timepoint

Patients will be seen on a daily basis from day 0 to day 4 and the timing of first POAF event will be recorded

Method of measurement

24-hour ECG holter monitoring

3

Description

Duration of incident post-op atrial fibrillation

Timepoint

Daily assessment from day 0 to day 4 until the first POAF event occurred and recording the duration of that.

Method of measurement

24-hour ECG holter monitoring

4

Description

Heart rate during incident first POAF event

Timepoint

Daily assessment from day 0 to day 4 until the first POAF event occurred and recording the HR during that.

Method of measurement

24-hour ECG holter monitoring

5

Description

Changes in heart rate after intervention

Timepoint

before and after intervention on a daily basis

Method of measurement

ICU monitoring device

6

Description

Changes in blood pressure after intervention

Timepoint

before and after intervention on a daily basis

Method of measurement

ICU monitoring device

7

Description

Changes in hs-CRP level

Timepoint

Days 0, 2 and 4

Method of measurement

Laboratory assessment

8

Description

Changes in NT-Pro BNP level

Timepoint

Days 0, 2 and 4

Method of measurement

Laboratory assessment

9

Description

Changes in CBC parameters

Timepoint

Days 0, 2 and 4

Method of measurement

Laboratory assessment

10

Description

Days of hospitalization

Timepoint

At discharge day

Method of measurement

The number of hospitalization days

Intervention groups

1

Description

Intervention group: Exposure to the active status of ta-VNS set to burst pulses of 30 on, 30 s off, 20 Hz frequency, 200 microseconds PW, and at 80% or 0.5 mA current on the left tragus. Active stimulation is turned on for 40 minutes, followed by 20 minutes of rest, and then 40 minutes of stimulation, starting from day 0 and repeated daily until discharge day or day 4.

Category

Treatment - Devices

2

Description

Control group: Exposure to sham status of ta-VNS that set to the same parameters as active, but transform no current. Sham stimulation is turned on for 40 minutes followed by 20 minutes rest, and then 40 minutes of stimulation, starting from day 0 and repeated daily until discharge day or day 4.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran heart center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

50

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

Danesh Soltani

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

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 is potentially shareable after individuals' identities have been removed.

When the data will become available and for how long

Considering that this study is a preliminary study, its data will be published after the main clinical trial.

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The use of data in secondary studies such as systematic reviews and meta-analyses is allowed.

From where data/document is obtainable

Correspondence with the email of the primary investigator of the study.

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

After reviewing the application in the research team, it will reach the applicant within 1 month.

Comments