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)

Phone
+98 21 2392 2189

Email address
avasheghani@tums.ac.ir

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 ≥ 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
Ali Vasheghani-Farahani
Street address
Tehran Heart Center, North Karegar street, Tehran
City
Tehran
Province
Tehran
Postal code
1411713138
Phone
+98 21 8802 9600
Email
avasheghani@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Vasheghani-Farahani
Street address
Poursina St., Ghods St., Keshavarz Blvd,Tehran 14176-53955, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1416634793
Phone
+98 21 8898 7381
Email
vcr@tums.ac.ir
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
Street address
Tehran Heart Center, North Karegar street, Tehran
City
Tehran

Province
Tehran
Postal code
1411713138
Phone
+98 21 8802 9256
Email
soltani.danesh@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Vasheghani-Farahani
Position
Fellowship of electrophysiology
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Tehran Heart Center, North Karegar st., Tehran
City
Tehran
Province
Tehran
Postal code
1411713138
Phone
+98 21 8802 9721
Fax
Email
avasheghani@tums.ac.ir
Web page address

Person responsible for updating data

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
Street address
Tehran Heart Center, North Karegar street, Tehran
City
Tehran
Province
Tehran
Postal code
1411713138
Phone
+98 21 8802 9256
Email
soltani.danesh@yahoo.com

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