Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Auricular Acupressure on Some Physical and Psychological Outcomes in Patients Undergoing Coronary Artery Bypass Graft Surgery Admitted to the Cardiac Intensive Care Unit: A Randomized Single-Blind Clinical Trial

Protocol summary

Study aim

To evaluate auricular acupressure versus sham acupressure or control on anxiety, pain, depression, physiological parameters (blood pressure, heart rate, respiratory rate), fatigue, sleep quality and delirium in elective coronary artery bypass grafting patients admitted to cardiac intensive care unit.

Design

Randomized single-blind sham-controlled three-arm parallel trial. N=96 (32/group). Stratified block randomization (age/gender/pre-op anxiety). Single-center.

Settings and conduct

Patients undergoing coronary artery bypass graft surgery admitted to the cardiac intensive care unit of Shahid Madani Hospital, Tabriz, who meet the inclusion criteria and provide informed consent, will be randomly assigned (1:1:1) to intervention (auricular acupressure), placebo, or control groups. This single-blind study will be conducted by an independent blinded analyst.

Participants/Inclusion and exclusion criteria

Inclusion: Age between 18 and 70 years, No prior history of coronary artery bypass surgery, Undergoing non-emergency coronary artery bypass surgery, Healthy external ear structure without abnormalities, Not concurrently participating in a similar study. Exclusion: Impaired consciousness (GCS score less than 15), Inability to communicate or understand instructions, Patient's statement of unwillingness to participate in the intervention.

Intervention groups

Intervention: Magnetic seeds at 10 auricular points; applied twice daily × 6 days (post-op day 2 onward). Sham: Identical magnetic seeds at non-acupoint sites; same frequency/duration. Control: Routine care only.

Main outcome variables

Anxiety, depression, Pain intensity, Physiological parameters (blood pressure, heart rate, respiratory rate), Fatigue, Sleep quality, delirium

General information

Reason for update

Due to the fact that a significant proportion of patients undergoing non-emergency coronary artery bypass graft (CABG) surgery at Shahid Madani Hospital in Tabriz are over 65 years old, the age inclusion criterion was changed from 18–65 years to 18–70 years. Furthermore, considering their greater clinical importance, the primary outcomes of the study were focused on pain, anxiety, and depression. This change resulted in the adjustment of the required sample size to 96 participants. In the measurement tools section, in addition to the Pittsburgh Sleep Quality Index (PSQI) which evaluates sleep changes over the past month, the Richards-Campbell Sleep Questionnaire was also added. This allows for the assessment of sleep changes in patients during their ICU stay and enables evaluation of both the short-term and long-term effects of the intervention on sleep outcomes. With the expansion of the age range, the secondary outcomes of the study were also broadened, and delirium was added to the secondary outcomes. In addition, the description of the sham group intervention was modified so that the magnetic beads are removed from the center of the patches to increase similarity to the placebo.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025937N9**
Registration date: **2025-09-04, 1404/06/13**
Registration timing: **prospective**

Last update: **2026-06-27, 1405/04/06**

Update count: **3**

Registration date

2025-09-04, 1404/06/13

Registrant information

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-20, 1405/03/30

Expected recruitment end date

2026-12-20, 1405/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Auricular Acupressure on Some Physical and Psychological Outcomes in Patients Undergoing Coronary Artery Bypass Graft Surgery Admitted to the Cardiac Intensive Care Unit: A Randomized Single-Blind Clinical Trial

Public title

Effect of Ear Acupressure on Recovery After Heart Surgery in Intensive Care Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 70 years. No prior history of coronary artery bypass surgery. Undergoing non-emergency coronary artery bypass surgery. Uniform anesthesiologist and anesthesia conditions for the patient. Surgery performed using a heart-lung machine. No history of psychological disorders (e.g., depression or major anxiety disorder) and no use of psychotropic medications No auricular acupressure received in at least the past 5 months. No intra-aortic balloon pump or pacemaker. No addiction to alcohol or drugs. No history of chronic pain (e.g., severe arthritis). Healthy external ear structure without abnormalities. Not concurrently participating in a similar study.

Exclusion criteria:

Impaired consciousness (GCS score less than 15). Inability to communicate or understand instructions. Patient's statement of unwillingness to participate in the intervention.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with a block size of 6 and 3 (to ensure balanced group allocation: 2 intervention, 2 placebo, 2 control per block or 1 intervention, 1 placebo, 1 control per block). Unit of Randomization: Individual patients. Randomization Strata: Stratification by: Age (≤60 years vs. >60 years) Gender (male vs. female) Preoperative anxiety score (HADS score ≤10 vs. >10). Tools Used: Random sequence generation: Random Allocation Software (RAS) version 2.0. Allocation concealment: Sequentially numbered, opaque, sealed envelopes (SNOSE). Random Sequence Building: An independent researcher generated the random sequence using RAS with a 1:1:1 allocation ratio. The sequence accounted for stratification factors (age, gender, anxiety). Assignments were printed, sealed in envelopes, and stored securely. Allocation Concealment: Yes, implemented via SNOSE. Envelopes were opened after patient enrollment and baseline assessments by a research nurse uninvolved in recruitment.

Blinding (investigator's opinion)

Single blinded

Blinding description

1. Participants Blinded: Yes Method: Identical procedures for Intervention (magnetic seeds on specific points) and Placebo (magnetic seeds on non-specific ear areas). Both groups receive "ear seed application" with identical appearance/duration (10 mins/session). Control group receives no ear contact to avoid inadvertent unblinding. 2. Intervention Providers Blinded: No Reason: Providers must apply seeds to specific vs. non-specific points, making blinding impossible. 3. Outcome Assessors Blinded: Yes Method: Assessors (data collectors) are separate from intervention providers. Use coded IDs (e.g., Group A/B/C) during data collection (anxiety, pain, physiological parameters). Prohibited from entering ICU during intervention sessions. 4. Principal Investigator (PI) Blinded: Partially Method: PI oversees trial but does not perform randomization, interventions, or outcome assessments. Unblinded only for adverse event monitoring. 5. Healthcare Providers Blinded: No Reason: Routine care may involve observing ear seeds, but they are instructed not to discuss group allocation with patients/assessors. 6. Data Analysts Blinded: Yes Method: Analyze anonymized datasets labeled as "Group A/B/C" without decoding until final analysis. 7. Data Safety Monitoring Board (DSMB) Blinded: No Reason:

DSMB requires unblinded data for safety oversight. 8. Manuscript Writers Blinded: Yes until analysis completion Method: Writers receive blinded results initially; unblinding occurs during interpretation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht ave., Tabriz, Iran

City

tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2025-06-02, 1404/03/12

Ethics committee reference number

IR.TBZMED.REC.1404.249

Health conditions studied

1

Description of health condition studied

anxiety following coronary artery bypass graft (CABG) surgery

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2

Description of health condition studied

acute pain following coronary artery bypass graft (CABG) surgery

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

3

Description of health condition studied

Hemodynamic instability following coronary artery bypass graft (CABG) surgery

ICD-10 code

ICD-10 code description

4

Description of health condition studied

fatigue following coronary artery bypass graft (CABG) surgery

ICD-10 code

ICD-10 code description

FATIGUE

5

Description of health condition studied

sleep disturbances following coronary artery bypass graft (CABG) surgery

ICD-10 code

F51

ICD-10 code description

Sleep disorders not due to a substance or known physiological condition

6

Description of health condition studied

depression following coronary artery bypass graft (CABG) surgery

ICD-10 code

ICD-10 code description

7

Description of health condition studied

delirium following coronary artery bypass graft (CABG) surgery

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes

1

Description

level of anxiety

Timepoint

Before surgery (baseline), at the time of transfer from the intensive care unit to the general surgical ward (the third day after surgery and the second day of receiving the intervention), at the time of hospital discharge (the seventh day after surgery and the sixth day of receiving the intervention), and one month after discharge (one month after the completion of the intervention).

Method of measurement

The Hospital Anxiety and Depression Scale (HADS) questionnaire.

2

Description

pain intensity

Timepoint

From the second postoperative day, measurements will be taken before and immediately after each intervention session (twice daily for 6 days).

Method of measurement

Visual Analogue Scale (VAS).

3

Description

Depression level.

Timepoint

Before surgery (baseline), at the time of transfer from the intensive care unit to the general surgical ward (the third day after surgery and the second day of receiving the intervention), at the time of hospital discharge (the seventh day after surgery and the sixth day of receiving the intervention), and one month after discharge (one month after the completion of the intervention).

Method of measurement

The Hospital Anxiety and Depression Scale (HADS) questionnaire.

Secondary outcomes

1

Description

severity of fatigue.

Timepoint

Before surgery (baseline), at the time of transfer from the intensive care unit to the general surgical ward (the third day after surgery and the second day of receiving the intervention), at the time of hospital discharge (the seventh day after surgery and the sixth day of receiving the intervention), and one month after discharge (one month after the completion of the intervention).

Method of measurement

Multidimensional Fatigue Inventory (MFI) questionnaire.

2

Description

sleep quality.

Timepoint

Before surgery (baseline), at the time of transfer from the intensive care unit to the general surgical ward (the third day after surgery and the second day of receiving the intervention), at the time of hospital discharge (the seventh day after surgery and the sixth day of receiving the intervention), and one month after discharge (one month after the completion of the intervention).

Method of measurement

Richards-Campbell Sleep Questionnaire in ICU and Pittsburgh Sleep Quality Index (PSQI) questionnaire.

3

Description

heart rate.

Timepoint

From the second postoperative day, measurements will be taken before and immediately after each intervention session (twice daily for 6 days).

Method of measurement

Cardiac monitoring device.

4

Description

respiratory rate.

Timepoint

From the second postoperative day, measurements will be taken before and immediately after each intervention session (twice daily for 6 days).

Method of measurement

direct observation

5

Description

body temperature.

Timepoint

From the second postoperative day, measurements will be taken before and immediately after each intervention session (twice daily for 6 days).

Method of measurement

Standard clinical thermometer.

6

Description

Systolic blood pressure

Timepoint

From the second postoperative day, measurements will be taken before and immediately after each intervention session (twice daily for 6 days).

Method of measurement

Cardiac monitoring device

7

Description

Diastolic blood pressure

Timepoint

From the second postoperative day, measurements will be taken before and immediately after each intervention session (twice daily for 6 days).

Method of measurement

Cardiac monitoring device

8

Description

delirium

Timepoint

Before surgery (baseline), at the time of transfer from the intensive care unit to the general surgical ward (the third day after surgery and the second day of receiving the intervention), at the time of hospital discharge (the seventh day after surgery and the sixth day of receiving the intervention), and one month after discharge (one month after the completion of the intervention).

Method of measurement

Confusion Assessment Method (CAM)-ICU-7 delirium

severity scale

Intervention groups

1

Description
Intervention group 1: Participants in this group will receive auricular acupressure. The procedure begins on the second postoperative day. After disinfecting the ear with 70% alcohol, patches containing magnetic seeds will be applied to specific auricular acupressure points (Shenmen, Spleen_c, Small Intestine, Kidney_c, Vagus nerve, Heart_c, Insomnia, San Jiao, and Liver). The researcher will then massage each point with the index finger using circular pressure for 1 minute, aiming to elicit the "Qi" sensation, for a total intervention time of 10 minutes per session. The intervention will be administered twice daily (morning and afternoon) for six consecutive days. To minimize skin irritation, the procedure will be performed on alternating ears each day.

Category
Treatment - Other

2

Description
Intervention group 2: Participants in this group will receive a sham acupressure procedure. After disinfecting the ear, magnetic seeds will be applied to non-specific points on the outer part of the ear, away from the true acupressure points. The researcher will then massage each point with the index finger using circular pressure for 1 minute, aiming to elicit the "Qi" sensation, for a total intervention time of 10 minutes per session. The intervention will be administered twice daily (morning and afternoon) for six consecutive days. To minimize skin irritation, the procedure will be performed on alternating ears each day.

Category
Treatment - Other

3

Description
Control group: Participants in this group will receive only the standard routine care provided to patients after coronary artery bypass graft surgery. No auricular acupressure or sham procedure will be administered. To ensure temporal consistency with the other groups, participants in the control group will be attended to for a 10-minute period at the same scheduled times, but no intervention will be performed.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Hospital
Full name of responsible person
Atefeh Allahbakhshian
Street address
Daneshgah street, Tabriz
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz 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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Aefeh Allahbakhshian
Position
Associate professor
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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
Deidentified Individual Participant Data (IPD): The shared dataset will include all collected deidentified IPD for each participant, covering demographic and clinical baseline characteristics, group allocation, and all primary and secondary outcome variables (HADS, VAS, MFI, PSQI, and physiological parameters) at all measurement timepoints as described in the protocol. Study Protocol: The final version of the study protocol as approved by the ethics committee. Statistical Analysis Plan (SAP): The detailed plan for the statistical analysis of the study data.
When the data will become available and for how long
The data will become available 6 months after the publication of the main trial results and will remain available for a period of 5 years.
To whom data/document is available
Data will be made available to qualified researchers affiliated with academic and research institutions.
Under which criteria data/document could be used

Access to the data will be granted for the purpose of re-analysis, meta-analysis, or other methodologically sound research. Requesters must submit a formal research proposal detailing the study's objectives, methodology, and analysis plan. All requests will be reviewed by the principal investigator to ensure the scientific validity and ethical soundness of the proposed use. Upon approval, the requester will be required to sign a data access agreement committing to protect participant confidentiality and use the data only for the approved purpose.

From where data/document is obtainable

Interested researchers can obtain the data by sending a formal request via email to the principal investigator: * Contact Person: Atefeh Allah Bakhshian * Email: atefehbakhshian@gmail.com

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

The process for accessing the data involves the following steps: * The applicant must submit a formal request via email to the principal investigator, including a detailed research proposal. * The request and proposal will be reviewed by the principal investigator and the research team, a process which may take up to 30 days. * If the request is approved, a data access agreement will be sent to the applicant. * The applicant must sign and return the data access agreement. * Upon receipt of the signed agreement, the deidentified individual participant dataset and relevant documents will be securely transferred to the applicant.

Comments