Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of transcutaneous electrical nerve stimulation at acupuncture points on hemodynamic indices and back pain in patients undergoing coronary artery catheterization: a randomized clinical trial

Protocol summary

Study aim
Determining the effect of TENS at acupoints on hemodynamic indices and back pain in patients undergoing coronary artery catheterization

Design
A randomized, double-blind, parallel clinical trial on 80 patients. Randomization was prepared from a sealed opaque envelope and each random sequence was recorded on a card. Randomization with Minitab software

Settings and conduct
In this double-blind study, 80 eligible patients were recruited using consecutive sampling. Random allocation was performed using four-block randomization with allocation concealment via opaque envelopes. Both participants and the data collector were blinded to group assignment, and data were collected blindly.

Participants/Inclusion and exclusion criteria
• Individuals 18-65 years old • Candidate for coronary angiography • Candidate for PCI via the femoral artery • Fully conscious and able to communicate . normal posterior tibial pulses

Intervention groups
In the intervention group, two 5×5 cm plastic electrodes are placed on pain-relief acupuncture points (GB30 and BL40) on the limb opposite to the Angiography site, and TENS is applied in burst mode at 90 Hz for 20 minutes. In the control group, electrodes are attached to non-related points (ST36 and SP6), and stimulation is delivered at a low frequency of 20 Hz for 20 minutes.

Main outcome variables
back pain and hemodynamic stability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250621066210N1**
Registration date: **2026-01-04, 1404/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-04, 1404/10/14**
Update count: **0**

Registration date
2026-01-04, 1404/10/14

Registrant information

Name
Abas Asadi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-31, 1404/10/10

Expected recruitment end date
2026-02-09, 1404/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of transcutaneous electrical nerve stimulation at acupuncture points on hemodynamic indices and back pain in patients undergoing coronary artery

catheterization: a randomized clinical trial

Public title
The effect of transcutaneous electrical nerve stimulation at acupuncture points on hemodynamic indices and back pain in patients undergoing coronary artery catheterization

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for coronary angiography Candidate for percutaneous coronary intervention via femoral artery Having full awareness and the power to communicate Presence of normal posterior tibia pulses Score higher than 3 for back pain using the NRS tool People 18 – 65 years old

Exclusion criteria:
Use of antihypertensive medication before and during the study Use of painkillers before and during the study Presence of back pain/low back pain in the past week before catheterization Back pain/low back pain at first evaluation after catheterization Patients with stroke, psychosis, history of trauma or blows that have caused damage to the limbs and disrupted the patient's sensation and movement. Complications during angiography, such as hematoma, infection, bleeding, cardiac arrhythmias, and cardiac arrest Cardiac conduction disorders (may be affected by TENS electrical stimulation) History of allergies and skin sensitivity in the area where the electrodes are to be placed The presence of a skin lesion in the area where the electrodes are to be placed Psychological illnesses leading to patient non-cooperation History of TENS (due to familiarity with TENS and the possibility of affecting results) The need for oxygen to follow up on the patient's condition after angiography

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is used to assign individuals to groups. Randomization is performed by generating random numbers from 1 to 80 (80 is the total number of individuals in the control and intervention groups) and assigning each number to one of the groups. This is done based on the sequence obtained from the software. For example, person number one is placed in the control or intervention group, depending on which group the number 1 is assigned to. Also, during randomization, equal numbers of men and women are assigned to the two groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The present study is triple-blind, meaning that the patients participating in the study are unaware of the type of group assigned (intervention and control). Also, the data collector and analyst will remain blind to the type of group assigned to the patients. Thus, the collection and recording of information including back pain, respiratory rate, pulse, oxygen saturation, and completion of the questionnaires will be done by a second person without knowing the group of individuals.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrood University of Medical Sciences

Street address
Shahid Foromandi Street - Foromandi 12

City
اسفراین

Province
North Khorasan

Postal code
9661938944

Approval date
2025-09-08, 1404/06/17

Ethics committee reference number
IR.SHMU.REC.1404.105

Health conditions studied

1

Description of health condition studied
Presence of coronary angioplasty implant and graft

ICD-10 code
Z95.5

ICD-10 code description
Presence of coronary angioplasty implant and graft

2

Description of health condition studied
Backache

ICD-10 code
M54.9
ICD-10 code description
Dorsalgia, unspecified

Primary outcomes

1

Description
Back pain • Score greater than 3 using the NRS tool
Timepoint
Before the intervention, 2, 4, and 6 hours after the intervention.
Method of measurement
Numerical rating scale

2

Description
Hemodynamic indicators
Timepoint
Before the intervention, 2, 4, and 6 hours after the intervention.
Method of measurement
Intrusive bedside monitoring and assessment device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Two 5x5 cm plastic electrodes are placed face to face or side by side at acupuncture points for pain relief (acupuncture points with the highest average effect size scores (GB30 and BL 40) connected to a BURJIS device, model ST90, manufactured in Iran and serial number ST90994090, and the burst mode and frequency will be set to 90 Hz and for a duration of 20 minutes. (The BL 40 point is located below the knee, and the GB30 point is located in the lower outer quarter of the gluteal muscle) and the pads will be attached to the leg opposite the angiography site (two small pads at each site, without the need to change the patient's position).
Category
Treatment - Other

2

Description
Control group: Two 5x5 cm plastic electrodes are attached at unrelated points (ST36, SP6, which have analgesic and anesthetic effects in the pelvic area and analgesia, respectively), and the burst mode and frequency will be set to 20 Hz (the lowest level) and for a duration of 20 minutes.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hassan Hospital
Full name of responsible person
Dr. Morteza Safikhani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud 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
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Abbas Asadi
Position
Student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
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