

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

effect of auricular acupressure on patient's comfort after coronary artery interventions

Protocol summary

Study aim

effect of auricular acupressure on patient's comfort after coronary artery interventions

Design

A clinical trial with a control group, randomized from among the available samples, on 84 patients, is used for randomization by envelope punching method.

Settings and conduct

Patients undergoing coronary artery interventions at Farshchian Heart Center, Hamadan, are randomly assigned to intervention and control groups. For the patients who are included in the intervention group, TF2, SF5, AT2 and HX1 points in the ear are identified and pressure plant labels are applied to these points and remain for 2 hours

Participants/Inclusion and exclusion criteria

Inclusion criteria : patients who are candidates for non-emergency radial coronary artery interventions, the ability to recognize the NRS scale, no mental disorders, the consent of the attending physician to participate in the research; Exclusion criteria: feeling comfortable in the patient, the presence of damage or malignancy in the ear area

Intervention groups

Patients who are included in the intervention group, ear acupressure with pressure plant labels is performed at TF2, SF5, AT2 and HX1 points

Main outcome variables

Comfort, pain and physiological indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231028059875N1**

Registration date: **2024-01-30, 1402/11/10**

Registration timing: **prospective**

Last update: **2024-01-30, 1402/11/10**

Update count: **0**

Registration date

2024-01-30, 1402/11/10

Registrant information

Name

Fatemeh Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-20, 1403/01/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of auricular acupressure on patient's comfort after coronary artery interventions

Public title

The effect of auricular acupressure on patient's comfort

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate patients for non-emergency radial coronary

artery interventions Ability to recognize NRS scale Consent of the attending physician to participate in the research Not having mental disorders with doctor's approval Exclusion criteria: Feeling comfortable and not having pain in the radial area Presence of damage and malignancy in the ear Age No age limit Gender Both Phase N/A Groups that have been masked No information Sample size Target sample size: 84 Randomization (investigator's opinion) Randomized Randomization description We will use the method of punching envelopes to randomize the samples; In this way, there are two separate envelopes, in envelope number one, there are 42 papers related to the acupressure intervention group with the letter A, and in envelope number 2, there are 42 papers in which the letter B means the control group. We put the envelopes it in front of the patient. And we ask him to take a number of papers from inside one of the envelopes randomly without switching. Depending on which one he chooses, the patient will be placed in the same group. Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features	2024-01-21, 1402/11/01 Ethics committee reference number IR.UMSHA.REC.1402.640 Health conditions studied <u>1</u> Description of health condition studied Coronary artery interventions (angiography and angioplasty) ICD-10 code Z98.61 ICD-10 code description Coronary angioplasty status Primary outcomes <u>1</u> Description Comfort Timepoint Before the intervention, 30 and 120 minutes after the intervention Method of measurement Numerical rating scale <u>2</u> Description Pain Timepoint Before the intervention, 30 and 120 minutes after the intervention Method of measurement Numerical rating scale <u>3</u> Description Heart rate Timepoint Before the intervention, 30 and 120 minutes after the intervention Method of measurement Number of beats per minute, pulse oximetry device <u>4</u> Description Mean arterial pressure Timepoint Before the intervention, 30 and 120 minutes after the intervention Method of measurement Sphygmomanometer <u>5</u> Description Oxygen saturation percentage of arterial blood
Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Hamadan university of medical science Street address Hamadan university of medical science, Shahid Fahmideh Blvd, Hamadan, Iran City Hamadan Province Hamadan Postal code ۶۵۱۷۸۳۸۷۳۶ Approval date	

Timepoint

Before the intervention, 30 and 120 minutes after the intervention

Method of measurement

pulse oximetry device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the intervention group, the benefits of acupressure and sticky plant seeds are explained, and patients are asked to ask any questions they may have. It will be explained to them that pressure plant labels will be placed on TF2, SF5, AT2 and HX1 points of their right ear for 2 hours. Then, the comfort of the patient, the severity of the patient's pain, the average arterial pressure, the heart rate and the oxygen saturation of the arterial blood will be measured three times at zero minute, 60 minutes later and 120 minutes after zero with the help of the available tools. It should be noted that minute zero is the moment the patient enters the ward

Category

Treatment - Devices

2**Description**

Control group: In relation to the control group, it should be noted that no specific intervention is performed and after that the research criteria include patient comfort, patient pain intensity, mean arterial pressure, heart rate and arterial blood oxygen saturation in three times at zero minutes. It will be checked 60 minutes later and 120 minutes after the zero minute. It is important to mention that both groups will not be deprived of the routine medical procedures that are performed in the department after coronary interventions

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

مرکز قلب فرشچیان

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Asadi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

After completing the research project and consulting with
the professors, I will make a decision about this

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