Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of auricular acupressure on anxiety levels and physiological indices of candidates for coronary angiography

Protocol summary

Study aim
Investigation of the effect of acupressure on the level of anxiety and physiological indices

Design
A controlled, parallel-group, single-blind, randomized clinical trial on 120 patients candidates for angiography. The random block is used for randomization.

Settings and conduct
Patients will be randomly divided into two groups, intervention and control, using block randomization. Participants will be unaware of their group assignment. For randomization, 30 random quadruplet blocks will be created. To conceal the randomization process, each of the generated random sequences will be written on separate cards and placed inside opaque envelopes. Samples will be allocated to intervention and control groups based on the order of the sequences listed on the envelopes. In both the intervention and control groups, the Shen Men and Sham points will be stimulated for ten minutes, respectively. In the control group, the sham point will be stimulated using a similar procedure to the intervention group.

Participants/Inclusion and exclusion criteria
Angiography candidate Willingness to participate in the study Having anxiety

Intervention groups
The study groups consist of two groups: the intervention group and the control group. In the intervention group, the Shen Men point will be stimulated for ten minutes using acupressure. In the control group, a similar intervention will be performed, but at the Sham point.

Main outcome variables
Anxiety, physiological indicators

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20100913004736N28**
Registration date: **2023-12-19, 1402/09/28**
Registration timing: **prospective**

Last update: **2023-12-19, 1402/09/28**
Update count: **0**

Registration date
2023-12-19, 1402/09/28

Registrant information
Name
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Name of organization / entity
Kermanshah University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-12-22, 1402/10/01
Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of auricular acupressure on anxiety levels and physiological indices of candidates for coronary angiography

Public title
The effect of acupressure on anxiety induced by angiography
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Angiography candidate Willingness to participate in the study Having anxiety No history of using acupressure No history of angiography
Exclusion criteria:
History of psychiatric diseases History of thyroid disease Smoking Cancellation of angiography
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants will be allocated to two intervention and control groups using random block allocation. Randomization unit: individual Randomization tool: statistical software The blocks will be generated using the software. Allocation concealment: This is a single-blind study, and the participants are unaware of their allocation to the intervention and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
To conceal the randomization process, each generated random sequence will be written on a separate card and placed inside opaque envelopes. The order of the sequences will be written on the envelopes. For example, envelope number one may contain the sequence (AABB), and the envelopes will be opened in numerical order. Each envelope will be used until the patients from that particular sequence have been assigned, and then the next envelope will be utilized.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Shahid Beheshti Blvd.,
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Province
Kermanshah
Postal code
6714634698
Approval date
2023-11-21, 1402/08/30
Ethics committee reference number
IR.KUMS.REC.1402.379

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41
ICD-10 code description
Other anxiety disorders

2

Description of health condition studied
Physiologic indexes
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Situational anxiety
Timepoint
Thirty minutes before and immediately after the intervention
Method of measurement
To measure anxiety, the State Anxiety Inventory (STAI) questionnaire is used.

2

Description
Blood pressure
Timepoint
Thirty minutes prior to and immediately after the intervention
Method of measurement
The blood pressure measurement is carried out using the Exacta 1350 analog sphygmomanometer made in Germany and the Duplex-4001 medical stethoscope also made in Germany. Prior to blood pressure measurement, the patient should refrain from consuming caffeine (coffee and tea) and smoking for at least thirty minutes. The patient is asked not to speak five minutes before the

blood pressure measurement. Then, the patient is positioned in a lying position on their back, comfortably on the bed, with their right arm extended along the side of their body and their palm facing upward. The blood pressure cuff of the mercury sphygmomanometer is then closed approximately 3-2 centimeters above the antecubital fossa of the right arm, and using the stethoscope, the systolic and diastolic blood pressure are measured. This is done by feeling the radial pulse while simultaneously inflating the cuff using the hand pump of the sphygmomanometer. When the pulse is no longer felt, the pressure in the manometer continues to rise until it reaches around 30 millimeters of mercury above the point of pulse disappearance. Then, the cuff is slowly deflated at a rate of 3-2 millimeters of mercury per second, while listening for Korotkoff sounds. The first sound corresponds to the systolic blood pressure. The point at which the sound becomes indistinct or gradually disappears completely represents the diastolic blood pressure.

3

Description
Pulse rate
Timepoint
Thirty minutes prior to and immediately after the intervention
Method of measurement
To measure the pulse rate, the radial artery pulse is counted for one minute.

4

Description
Arterial blood oxygen saturation (SpO2)
Timepoint
Thirty minutes prior to and immediately after the intervention
Method of measurement
To measure arterial blood oxygen saturation, the Beurer PO30 fingertip pulse oximeter, made in Germany, is used. For this purpose, the probe of the device is placed on the right index finger for a duration of 10 seconds, and then the value displayed on the monitor is recorded as the arterial blood oxygen saturation level.

5

Description
Respiratory rate
Timepoint
Thirty minutes prior to and immediately after the intervention
Method of measurement
To measure the respiratory rate and chest movements, the number of chest wall movements is counted for one minute simultaneously with the pulse rate measurement.

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, 30 minutes before angiography, the Shen Men point located in the upper wall of the ear cavity is stimulated bilaterally using a specialized acupressure pen called "Picsor" manufactured in China for a duration of 10 minutes.
Category
Treatment - Other

2

Description
In the control group, a sham point located at the outer corner of the ear cavity is used. 30 minutes before angiography, this point is stimulated bilaterally using a specialized acupressure pen called "Picsor" manufactured in China for a duration of 10 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Hospital
Full name of responsible person
Alireza Khatony
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah 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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Alireza Khatony

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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