

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Alireza Khatony

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3827 9394

Email address

akhatony@kums.ac.ir

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 acupuncture 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 acupuncture 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.,

City

Kermanshah

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

Street address

Shahid Beheshti St.

City

Kermanshah

Province

Kermanshah

Postal code

6714634698

Phone

+98 83 3827 9394

Email

akhatony@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Cyrus Jalili

Street address

Shahid Beheshti Ave.,

City

Kermanshah

Province

Kermanshah

Postal code

6714634698

Phone

+98 83 3838 4185

Email

Cjalili@kums.ac.ir

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

Street address

Shahid Beheshti Blvd.,

City

Kermanshah

Province

Kermanshah

Postal code

6714634698

Phone

+98 83 3827 9394

Email

akhatony@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Alireza Khatony

Position

Kermanshah University of Medical Sciences

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Other areas of specialty/work

Nursery

Street address

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Province

Kermanshah

Postal code

6714634698

Phone

+98 83 3827 9394

Email

akhatony@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Alireza Khatony

Position

Professor

Latest degree

Ph.D.

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Email

akhatony@gmail.com

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