

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of auriculotherapy on the level of situational anxiety and heart-focused anxiety of candidates for angiography

Protocol summary

Study aim

Evaluating the efficacy of auriculotherapy on situational and heart-focused anxiety in angiography candidates

Design

Phase III double-blind randomized sham-controlled trial with parallel groups on 138 patients, randomization performed using a randomization table generated by the Random Allocation software

Settings and conduct

This study will be performed on 138 angiography candidates admitted to the CCU and post-CCU wards of Shahid Mohammadi hospital, BandarAbbas. Patients will be randomized into two groups based on a randomization table. In the intervention group, one hour before angiography, auriculotherapy will be performed with thumb and a plastic bead using mild pressure for 10 min on the Shenmen point in the non-dominant ear, and in the control group, one hour before angiography, acupressure will be performed on a false point and not the main point for 10 min in the non-dominant ear. The main outcome (anxiety) evaluation is done by patients, and the physiological indicators by the researcher, who are blinded to groupings, resulting in a double-blind research.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 years or older, literacy, candidacy for coronary angiography Exclusion criteria: Simultaneous participation in other interventional research projects, having participated in anxiety management educational courses, drug or alcohol abuse, taking anti-psychotic medications, structural disorders of the external ear, previous angiography, cognitive or psychiatric disorders

Intervention groups

Intervention group: One hour before angiography, auriculotherapy with thumb and a plastic bead using mild pressure for 10 min on the Shenmen point in the non-dominant ear Control group: One hour before angiography, acupressure on a false point and not the

main point for 10 min in the non-dominant ear

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230108057076N1**

Registration date: **2023-02-15, 1401/11/26**

Registration timing: **prospective**

Last update: **2023-02-15, 1401/11/26**

Update count: **0**

Registration date

2023-02-15, 1401/11/26

Registrant information

Name

Ehsan Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 3280

Email address

ehsan3513@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of auriculotherapy on the level of situational anxiety and heart-focused anxiety of candidates for angiography

Public title
Auriculotherapy for anxiety in angiography candidates

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 years or older Literacy Candidacy for coronary angiography
Exclusion criteria:
Simultaneous participation in other interventional research projects Having participated in anxiety management educational courses Drug or alcohol abuse Taking anti-psychotic medications Structural disorders of the external ear Previous angiography Cognitive or psychiatric disorders

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **138**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomized into two groups using simple randomization with individuals as the unit of randomization and a randomization table produced by the Random Allocation software. An individual uninformed in the study will write A or B on a card and put it in an opaque envelope. Then the associated number in the randomization table will be written on the back of the envelope. One envelope will be allocated to each patient in order of entrance to the study. Allocation concealment will be done using opaque envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
In the control group, the pressure will be on the false points and the patients will receive the interventions independently of each other and in the order of entering the study. The evaluation of the main outcome, i.e. anxiety, is done by the patient himself, who will be unaware of the grouping, and the evaluation of the physiological indicators is done by the researcher, who is not aware of the grouping of the patients. Therefore, both the participants and the evaluator will be blinded

and the study will be conducted in a double-blind manner.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences
Street address
Faculty of Medicine, Across from Kargaran Sports Complex, Imam Hossein Blvd.
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885

Approval date
2022-04-24, 1401/02/04

Ethics committee reference number
IR.HUMS.REC.1401.015

Health conditions studied

1

Description of health condition studied
Anxiety in angiography
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Situational anxiety
Timepoint
10 min before and 30 min after intervention
Method of measurement
Spielberger`s State-Trait Anxiety Inventory

2

Description
Heart-focused anxiety
Timepoint
10 min before and 30 min after intervention

Method of measurement

Eifert's Cardiac Anxiety Questionnaire

Secondary outcomes

1

Description

Blood pressure

Timepoint

10 min before and 30 min after intervention

Method of measurement

Beurer's sphygmomanometer

2

Description

Heart rate

Timepoint

10 min before and 30 min after intervention

Method of measurement

Beurer's pulse oximeter

3

Description

Arterial oxygen saturation

Timepoint

10 min before and 30 min after intervention

Method of measurement

Beurer's pulse oximeter

4

Description

Body temperature

Timepoint

10 min before and 30 min after intervention

Method of measurement

Beurer's thermometer

Intervention groups

1

Description

Intervention group: One hour before angiography, auriculotherapy with thumb and a plastic bead using mild pressure for 10 min on the Shenmen point in the non-dominant ear

Category

Treatment - Other

2

Description

Control group: One hour before angiography, acupressure on a false point and not the main point for 10 min in the non-dominant ear

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Ehsan Karimi

Street address

Shahid Mohammadi Hospital, Jomhuri Eslami Blvd., Hormozgan, Iran

City

Bandar Abbas

Province

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Email

shmh@hums.ac.ir

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery for Research Hormozgan University of Medical Sciences

Full name of responsible person

Teamur Aghamolaei

Street address

Faculty of Medicine, Across from Kargaran Sports Complex, Imam Hossein Blvd.

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Web page address

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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

Vice-Chancellery for Research Hormozgan 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**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Ehsan Karimi

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Fax**Email**

ehsan3513@gmail.com

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

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available