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 resrearcher, 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)

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+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 uninvolved 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, Jomhouri Eslami Blvd., Hormozgan, Iran
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Postal code
9791991551
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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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teaghamolaei@gmail.com
Web page address
https://resv.hums.ac.ir/
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
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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
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