

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of Auriculotherapy on anxiety in elderly candidates for coronary angiography

Protocol summary

Study aim

Determining the effect of Auriculotherapy on anxiety in elderly patients candidates for coronary angiography

Design

Three-group randomized trial with parallel, single-blind groups on 90 elderly

Settings and conduct

This study will be performed on 90 elderly candidates for angiography referred to the special clinic of Ghaem Hospital in Mashhad. Research units will be randomly assigned to three groups (intervention 1 and 2 and control). In the intervention groups, bead and non-bead labels were placed on one ear at the Shenman, Relaxation, Tranquilizer, and Endocrine points from three days before angiography, and patients will press each label three times a day with their finger for one minute. There will be no intervention in the control group. All three groups will also receive routine ward care. Anxiety will be assessed using the Spielberger questionnaire before the intervention and three days after the intervention (half an hour before the angiography).

Participants/Inclusion and exclusion criteria

1. Having an age of over 60 years old
2. Be literate for the patient or a close family member
3. Doing angiography for the first time
4. Non-emergency angiography
5. Not undergoing complementary therapies
6. No ear lesions (sores, eczema, urticaria, etc.)
7. No history of cases such as: cognitive disorders, anxiety, stress and depression, Parkinson's, Alzheimer's based on medical history of the patients, use sedatives drugs and previous auriculotherapy

Intervention groups

Intervention group 1: (n=30), people in this group will press the places marked by Magnetic bead labels on the ear at certain times, intervention group 2: (n=30), People in this group will press on the places marked by the beadless labels on the ear at certain times, the control group (n=30), people in this group will not receive any intervention.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220119053765N1**

Registration date: **2022-04-14, 1401/01/25**

Registration timing: **prospective**

Last update: **2022-04-14, 1401/01/25**

Update count: **0**

Registration date

2022-04-14, 1401/01/25

Registrant information

Name

najmeh zeinali

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3741 1246

Email address

najmehzeinaly@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-16, 1401/01/27

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Auriculotherapy on anxiety in elderly candidates for coronary angiography

Public title

The effect of Auriculotherapy on anxiety

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age older than 60 years old Be literate The patient or a close family member of the patient Doing angiography for the first time

Exclusion criteria:

Non-emergency angiography Not undergoing complementary therapies No ear lesions (sores, eczema, urticaria, etc.) No history of cases such as: cognitive disorders, anxiety, stress and depression, Parkinson's, Alzheimer's based on medical history of the patients, use sedatives drugs, and previous auriculotherapy

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study will not know the type of intervention received.

Blinding (investigator's opinion)

Single blinded

Blinding description

Sampling in this study will be initially purposeful method and according to the inclusion criteria and then random assignment of individuals to three groups through permutation blocks. First, with the help of computer software, a list of random codes with a permutation block approach proportional to the estimated sample size, ie at least 90 people in three groups will be generated. So the eligible seniors will receive a unique code in order of identification and will be placed in each of the three study groups. At online software (<https://www.sealedenvelope.com>) will be used for permuted block randomization.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of North Khorasan University of Medical Sciences

Street address

Central Building of North Khorasan University of Medical Sciences, Dolat Blvd, Bojnurd

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Bojnurd

Province

North Khorasan

Postal code

7487794149

Approval date

2022-01-10, 1400/10/20

Ethics committee reference number

IR.NKUMS.REC.1400.151

Health conditions studied**1****Description of health condition studied**

Aanxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes**1****Description**

Anxiety score in the elderly Candidate for coronary angiography

Timepoint

At the beginning of the study (before the intervention) and three days after the intervention (half an hour before angiography)

Method of measurement

Spielberger state- trait anxiety inventory

Secondary outcomes

empty

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

Intervention group 1: In this group, from three days before angiography, Magnetic bead labels, in Shenman,

relaxation, tranquilizer and endocrine points are placed on one ear and patients will be asked to press each label three times a day by finger for one minute.

Category

Treatment - Devices

2**Description**

Intervention group 2: In this group, three days before angiography, beadless labels, in Shenman, relaxation, tranquilizer and endocrine points are placed on one ear and patients will be asked to press each label three times a day by finger for one minute.

Category

Treatment - Devices

3**Description**

Control group: There will be no intervention in the control group and routine care will be performed.

Category

N/A

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

Special clinic of Ghaem Hospital in Mashhad

Full name of responsible person

Marjaneh Farazestanian

Street address

Ahmadabad St., Ghaem Hospital

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

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Amir Ali Ghahremani (Deputy of Research and Technology)

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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

Bojnourd University of Medical Sciences

Proportion provided by this source

99

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

2**Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour Mobarhan (Deputy of Research and Technology)

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University Street, next to Hoveyze Cinema, Ghorashi Building, Deputy of Research and Technology

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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

Mashhad University of Medical Sciences

Proportion provided by this source

1

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

Full name of responsible person

Najmeh Zeinali

Position

Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Full name of responsible person

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Postal code**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