Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
City
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 Hoveyzeh 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

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
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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