Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

The effect of auriculotherapy on physiological and psychological criteria in patients before coronary angiography.

Protocol summary

Study aim
The effect of auriculotherapy on physiological and psychological criteria in patients before coronary angiography

Design
The single-blind clinical trial and by coin-throwing patients were divided into groups, intervention and control.

Settings and conduct
This study was performed in the selected hospital of AJA University of Medical Sciences (502 Tehran Hospital).Angiography Unit, in 1398. This is a single-blind study. The method of auriculotherapy was described for both control and intervention groups, and only patients did not know that they were in control or intervention groups.

Participants/Inclusion and exclusion criteria
1. Age less than 70 years. 2. Literacy in reading and writing. 3. Perform angiography for the first time. 4. Angiography is not the type of emergency.

Intervention groups
Auriculotherapy is a technique in which a person feels relaxed by touching a specific point in the ear, Ericulotherapy was performed on the intervention group and touch of false ear in the control group.

Main outcome variables
1. Anxiety 2. Stress 3. systolic blood pressure 4. Diastolic blood pressure 5. Breathing rate 6. Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190113042348N1**
Registration date: **2020-03-06, 1398/12/16**
Registration timing: **retrospective**
Last update: **2020-03-06, 1398/12/16**
Update count: **0**

Registration date
2020-03-06, 1398/12/16

Registrant information

Name
Vahid Rahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8847 7976

Email address
vahid.4246@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-08-20, 1398/05/29

Actual recruitment start date
2019-07-23, 1398/05/01

Actual recruitment end date
2019-08-20, 1398/05/29

Trial completion date
2019-08-20, 1398/05/29

Scientific title
The effect of auriculotherapy on physiological and psychological criteria in patients before coronary angiography.

Public title
Effect of auriculotherapy on physiological and psychological Parameters, in patients undergoing coronary angiography in selected hospitals of AJA University of Medical Sciences

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Reading and writing skills Age less than 70 years Perform angiography for the first time No ear ulcer Do not have a history of hospitalization in the heart department. Angiography is not an emergency. They have not previously undergone other invasive procedures such as Transesophageal echocardiography Do not have a history of known heart valve diseases Do not have physical disabilities. No serious psychiatric disorder Do not be part of the medical staff Their first-degree relatives have not previously had coronary angiography

Exclusion criteria:

Drug Addiction History of performing auriculotherapy Do not have a history of anxiety and depression based on findings in the file. Serious psychiatric disorder based on findings in the file. Do not be part of the medical staff.

Age

From **18 years** old to **70 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **94**

Actual sample size reached: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were selected by convenience sampling and were randomly divided By throwing coins into two groups of intervention and control.

Blinding (investigator's opinion)

Single blinded

Blinding description

For patients, the method of auriculotherapywas explained, but none of the samples knew that they were in the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AJA University of Medical Sciences

Street address

Army University of Medical Sciences, Shahid Etemadzadeh Street, West Fatemi Ave, Tehran

City

Tehran

Province

Tehran

Postal code

1613/635751

Approval date

2019-04-28, 1398/02/08

Ethics committee reference number

IR.AJAUMS.REC.1398.025

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

Before the intervention, DASS21 will be filled in by patients and 60 minutes before angiography will be performed at predetermined angiography, for 4 minutes and 1 minute at each point. ,. Ten minutes after the auriculotherapy intervention, the DASS21 scale was again filled by the patients.

Method of measurement

Anxiety and Stress Measurement Questionnaire DASS-21

Secondary outcomes

1

Description

Anxiety

Timepoint

Anxiety variable was assessed by DASS_21 questionnaire one hour before and ten minutes after intervention.

Method of measurement

Questionnaire DASS_21

2

Description

Stress

Timepoint

One hour before and ten minutes after intervention the

stress variable was assessed by DASS_21 questionnaire.

Method of measurement

Questionnaire DASS_21

3

Description

Systolic blood pressure

Timepoint

One hour before and ten minutes after intervention diastolic blood pressure was measured by sphygmometer model BC 80.

Method of measurement

Sphygmometer model BC 80 Made in Germany

4

Description

Diastolic blood pressure

Timepoint

One hour before and ten minutes after the intervention, diastolic blood pressure was measured by a sphygmometer.

Method of measurement

sphygmometer model BC 80 Made in Germany

5

Description

Respiratory rate

Timepoint

One hour before and ten minutes after the intervention, the variable respiratory rate was counted by the researcher in one minute.

Method of measurement

The respiratory rate was counted by the researcher in one minute

6

Description

pulse rate

Timepoint

One hour before and ten minutes after the intervention, the variable pulse rate was counted by the researcher in one minute.

Method of measurement

The number of radial pulses was counted by the researcher in one minute

Intervention groups

1

Description

Intervention group: Acupressure (auriculotherapy) was performed by the researcher 60 minutes before angiography at predetermined points. Using the thumb, gentle counter-pressure was applied to the counterclockwise for 4 minutes at each point for 1 minute.

Category

Prevention

2

Description

Control group: Acupressure (auriculotherapy) was performed by the researcher 60 minutes before angiography at predetermined points. But the auriculotherapy was performed in the false points in the ear.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran 502 Hospital

Full name of responsible person

Vahid rahimi

Street address

North Spring Street corner, Taleghani street, Tehran

City

Tehran

Province

Tehran

Postal code

6717855379

Phone

+98 21 8882 2222

Fax

+98 21 8882 8001

Email

zahrafarsi@gmail.com

Web page address

https://www.ajaums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Dr Zahra Farsi

Street address

Army University of Medical Sciences, Shahid Etemadzadeh Street, West Fatemi Ave, Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

arasajadi@yahoo.com

Web page address

http://www.ajaums.ac.ir/page/contact-us/

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Dr Zahra Farsi
Position
Research Assistant
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Army Nursing School, Next to Army Khanevadeh Hospital, opposite Khor St., Shariati Ave., Shiraz Ave., Tehran
City
Tehran
Province
Tehran
Postal code
۱۶۱۵۱۱۶۱۳۹
Phone
+98 21 7750 0404
Fax
+98 21 7750 0404
Email
zahrafarsi@gmail.com
Web page address
https://nursing.ajaums.ac.ir/page/research-helpmeet/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Dr Azam Sadjadi
Position
Director of Education
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Army Nursing School, Next to Army KhanevadehHospital, opposite Khor St., Shariati Ave., Shiraz Ave., Tehran
City
Tehran
Province
Tehran
Postal code
۱۶۱۵۱۱۶۱۳۹
Phone
+98 21 7750 0929
Email
arasajadi@gail.com
Web page address
http://nursing.ajaums.ac.ir/page/introduction-to-education-manager/

Person responsible for updating data

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Vahid Rahimi
Position
دانشجو
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Army Nursing School, Next to Army Khanevadeh Hospital, opposite Khor St., Shariati Ave., Shiraz Ave., Tehran
City
Teharan
Province
Tehran
Postal code
۱۶۱۵۱۱۶۱۳۹
Phone
+98 21 8850 4241
Email
vahid.4246@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

All postgraduate students of medical sciences and researchers and professors of medical universities of Iran.

From where data/document is obtainable

Faculty of Nursing, Army University of Medical Sciences, Vice Chancellor for Research, Dr. Zahra Farsi

What processes are involved for a request to access data/document

It takes about 1 month to access the information through the faculty

Comments