

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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

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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 auriculotherapy was 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

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North Spring Street corner, Taleghani street, Tehran

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

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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**  
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

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Army Nursing School, Next to Army Khanevadeh Hospital, opposite Khor St., Shariati Ave., Shiraz Ave., Tehran

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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**