

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jul 2026

### Comparison of the effects of relaxation and meditation techniques on serum levels of IL-2, TNF- $\alpha$ , IL-17A and IL-23 in the patients with coronary artery disease who refer to the outpatient heart clinic in 2018

#### Protocol summary

##### Study aim

Determining the comparative effect of two methods of relaxation and meditation on serum levels of IL-2, TNF- $\alpha$ , IL-17A and IL-23 cytokines in patients with coronary artery disease referred to the outpatient cardiology clinic in 2018

##### Design

A clinical trial study has a control group with parallel, one-blind, and randomized groups.

##### Settings and conduct

Patients are selected from patients with coronary artery disease referred to the outpatient clinic of Rafsanjan University of Medical Sciences. After obtaining informed consent, individuals will be randomly assigned to the above groups. Intervention for relaxation and meditation is done for each of the groups; Before the study begins and three months after the start of the study, the blood sample is taken from the patient.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: known coronary artery disease (based on medical records), history of hospitalization in the CCU, willingness to participate in the study. Exclusion criteria: History of mental illness or using psychiatric drugs, History of heart failure, The history of autoimmune diseases, allergies and immune-related diseases.

##### Intervention groups

For a group, meditation intervention is performed and relaxation intervention is performed for a group. The control group receives routine care.

##### Main outcome variables

serum levels of IL-2, TNF- $\alpha$ , IL-17A and IL-23 cytokines in patients with coronary artery disease

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20150519022320N16**

Registration date: **2019-01-05, 1397/10/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-05, 1397/10/15**

Update count: **0**

#### Registration date

2019-01-05, 1397/10/15

#### Registrant information

##### Name

Tayebeh Mirzaei

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3425 5900

##### Email address

t.mirzaei@rums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-10-23, 1397/08/01

#### Expected recruitment end date

2019-01-20, 1397/10/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effects of relaxation and meditation

techniques on serum levels of IL-2, TNF- $\alpha$ , IL-17A and IL-23 in the patients with coronary artery disease who refer to the outpatient heart clinic in 2018

## Public title

Comparative effect of two methods of relaxation and meditation on serum levels of IL-2, TNF- $\alpha$ , IL-17A and IL-23 cytokines

## Purpose

Basic science

## Inclusion/Exclusion criteria

### Inclusion criteria:

Known coronary artery disease (based on medical records); History of admission in section CCU Expression of willingness to participate in the study

### Exclusion criteria:

History of heart failure History of mental illness or use of psychoactive drugs, The history of autoimmune diseases, allergies and immune-related diseases

## Age

From **45 years** old to **75 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Data analyst

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

According to the criteria for Inclusion, a list of 90 eligible patients is available. The names of people are then placed in vague envelopes, and a researcher puts the envelopes in 3 groups of 1, 2, 3, Then they are selected according to the lottery of 1,2,3 groups to meditation, relaxation and control groups.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Tests are conducted by a researcher who does not know about the allocation of participants in study groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee on Research in Rafsanjan University of Medical Sciences

## Street address

Imam Ali Blvd, Central Office of the University of Medical Sciences

## City

Rafsanjan

## Province

Kerman

## Postal code

7717933777

## Approval date

2018-10-20, 1397/07/28

## Ethics committee reference number

IR.RUMS.REC.1397.122

## Health conditions studied

### 1

#### Description of health condition studied

Coronary Artery Disease

#### ICD-10 code

I25

#### ICD-10 code description

Chronic ischemic heart disease

## Primary outcomes

### 1

#### Description

Measuring the serum level of IL-17A

#### Timepoint

Before the start of the study and three months after the start of the study

#### Method of measurement

ELISA test

### 2

#### Description

Measuring the serum level of IL-23

#### Timepoint

Before the start of the study and three months after the start of the study

#### Method of measurement

ELISA test

### 3

#### Description

Measuring the serum level of IL-2

#### Timepoint

Before the start of the study and three months after the start of the study

#### Method of measurement

ELISA test

### 4

#### Description

Measuring the serum level of TNF- $\alpha$

#### Timepoint

Before the start of the study and three months after the start of the study

**Method of measurement**  
ELISA test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: A relaxation program will be planned and implemented in seven stages for the relaxation group, the steps of which will be: 1. Identify the muscles and muscle groups of the case, 2- Training on progressive muscle relaxation technique using its explanation and practical presentation by the researcher, 3- Answering the patient's questions about the relaxation technique 4- Performing the technique by the researcher using an audio tape, or educational CD 5- Performing the technique by the patients along with the researcher, 6- Statement of difference in physical and mental feelings of samples after relaxation 7- Performing the technique by samples and under the supervision of the researcher. In relaxation, patients will be asked to first shrink and then loosen the muscles of the muscles of the foot to the muscles of the face, including 16 muscles. Patients relax their muscles by counting up to number 5 and then relaxing by counting up to 10. The same steps will be repeated for the legs, legs, thighs, abdomen, chest, hips, arms and forearms, arms, shoulders, neck, forehead, tongue and jaw, eyes and face until all of their bodies Loose integrated. At the same time, patients breathe deeply during relaxation. The state of choice for gradual relaxation is lying. The patient will perform this exercise until the difference between the contraction and the muscle tone is felt and expressed. In this way, the method will be taken and can take this method alone and using a tape. After ensuring the correct understanding and correctness of the procedure, audio cassettes and CDs will be provided to patients for the implementation of relaxation steps. And they spend three months (three times a week) one day in a row and for a half an hour under the supervision of the researcher (a total of 36 sessions).

#### Category

Lifestyle

### 2

#### Description

Intervention group 2: To perform meditation, the patient is asked to be in a comfortable position and perform a deep inhale with 3 numbers and a deep exhalation with 4 numbers; Meditation will be performed for 8 weeks, 3 days a week, and 15 to 20 minutes per day in two steps in the morning and in the evening.

#### Category

Lifestyle

### 3

#### Description

Control group: The control group includes patients who receive routine methods such as medical and medical services.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Heart clinic

##### Full name of responsible person

Mahbobeh kafizadeh

##### Street address

Parastar Ave.

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7718796755

##### Phone

+98 34 3425 5900

##### Email

kafizadehm@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Ali Shamsizadeh

##### Street address

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info@rums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Rafsanjan 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**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Tayebeh Mirzaei

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Mohammad Kazemi Arababadi

**Position**

Associate professor

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Ph.D.

**Other areas of specialty/work**

Immunology

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**Person responsible for updating data****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Mohadeseh Raeisi

**Position**

Non-faculty

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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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