

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparison of the effects of relaxation and meditation techniques on serum levels of IL-10, TGF- $\beta$ , IL-6 and IFN- $\gamma$ in the patients with Coronary Artery Disease

#### Protocol summary

##### Study aim

Determining the Comparison of the effects of relaxation and meditation techniques on serum levels of IL-10, TGF- $\beta$ , IL-6 and IFN- $\gamma$  in the patients with Coronary Artery Disease

##### Design

The research sample consisted of 90 participants. This clinical trial study has 3 groups with parallel 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

The criteria for Inclusion the study are: known coronary artery disease (based on medical records), history of hospitalization in the CCU, no history of mental illness or lack of use of psychoactive drugs, willingness to participate in the study, Lack of heart failure, Lack of autoimmune diseases, Lack of allergies and immune-related diseases

##### Intervention groups

The sample consisted of 90 participants: , 30 people with coronary artery stenosis receiving routine methods, 30 people with coronary artery stenosis in meditation group, 30 people with coronary artery stenosis are in the relaxation group.

##### Main outcome variables

Determination of Serum Levels of IL-10, TGF- $\beta$ , IL-6, and IFN- $\gamma$  Cytokines in Patients with Coronary Artery Disease

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150519022320N18**

Registration date: **2019-01-27, 1397/11/07**

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

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

##### Registration date

2019-01-27, 1397/11/07

##### 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

2018-12-04, 1397/09/13

##### Expected recruitment end date

2019-02-19, 1397/11/30

##### 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-10, TGF- $\beta$ , IL-6 and IFN- $\gamma$  in the patients with Coronary Artery Disease

### Public title

Comparison of the effects of relaxation and meditation techniques on serum levels of IL-10, TGF- $\beta$ , IL-6 and IFN- $\gamma$

### Purpose

Basic science

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Known coronary artery disease (based on medical records) Background in the CCU Lack of history of mental illness or lack of use of psychoactive drugs Desire to participate in the study Lack of heart failure Lack of autoimmune diseases, allergies and immune-related diseases Age range 45 to 75 years

#### Exclusion criteria:

### Age

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

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Investigator

### Sample size

Target sample size: **90**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The sampling will be based on objective criteria for inclusion. After obtaining informed consent, subjects randomly to be divided into groups. By random numbers, each person is assigned a number. They were then randomly assigned to relaxation and meditation groups.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Experiments are conducted by a researcher who does not know about the grouping of participants in the study.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

کمیته اخلاق در پژوهش دانشگاه علوم پزشکی رفسنجان

#### Street address

بلوار امام علی، سازمان مرکزی سازمان مرکزی دانشگاه علوم پزشکی

#### City

رفسنجان

#### Province

Kerman

#### Postal code

7717933777

#### Approval date

2018-10-20, 1397/07/28

#### Ethics committee reference number

IR.RUMS.REC.1397.121

## Health conditions studied

### 1

#### Description of health condition studied

Atherosclerotic heart disease

#### ICD-10 code

I25

#### ICD-10 code description

Chronic ischemic heart disease

## Primary outcomes

### 1

#### Description

Measuring the level of serum IL-6

#### Timepoint

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

#### Method of measurement

ELISA test

### 2

#### Description

Measuring the level of serum IL-10

#### Timepoint

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

#### Method of measurement

ELISA test

### 3

#### Description

Measuring the level of serum TGF- $\beta$

#### Timepoint

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

#### Method of measurement

ELISA test

### 4

#### Description

Measuring the level of serum IFN- $\gamma$

### **Timepoint**

Before 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 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: 30 people with coronary artery disease without any intervention. Blood samples are taken before and three months after the study.

##### **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 shamsi zadeh

###### **Street address**

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

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###### **Phone**

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###### **Email**

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**

Assistant Professor

**Latest degree**

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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**Email**

mraesi@ymail.com

**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