

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- α , 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- α , 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- α , 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

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Name of organization / entity

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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-α, 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-α, 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-α 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

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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