Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Name
Tayebeh Mirzaei

Name of organization / entity
Rafsanjan University of Medical Sciences

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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 scienece

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 analyser

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

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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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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

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

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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