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-10, TGF-β, IL-6 and IFN-γ 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-β, IL-6 and IFN-γ 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-β, IL-6, and IFN-γ 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

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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-β, IL-6 and IFN-γ 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-β, IL-6 and IFN-γ

Purpose
Basic scienece

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-β
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-

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
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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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Province
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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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Person responsible for updating data

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Bachelor
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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