

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of long-term combination training (rehabilitation-yoga) on some of the pre-inflammatory factors and depression levels in coronary artery disease patients after surgery.

Protocol summary

Study aim

The effect of long-term combination therapy (rehabilitation-yoga) on some of the pre-inflammatory factors and depression levels in coronary artery disease patients after surgery.

Design

Samples were randomly selected from male patients who underwent coronary artery bypass graft surgery at the Shahid Rajaie Cardiology Center and were in Phase 2 discharge. Patients are randomly assigned into two groups of rehab and yoga-rehabilitation. In order to randomize at this stage, the names of people in the envelope and the codes defined on them by one person (other than the administrators) in two groups of control (rehearsal practice) and experimental group (combined practice) randomly are divided.

Settings and conduct

The control group and the combined exercises group should be present at the rehabilitation department of Tehran's Shahid Rajaie Cardiology Hospital during the course of the project (8 weeks), weekly three sessions per week. The intensity of the rehabilitation exercises in this plan is between 60-85% of the maximum heart rate, depending on the subject's ability.

Participants/Inclusion and exclusion criteria

Patients with coronary artery bypass grafts and male gender. Use of the same drugs at the time of the study. No history of heart surgery - no motor and orthopedic problems - Not having distance more than 100 km from the rehab center - ejection fraction no less than 35%.

Intervention groups

Control group (cardiac rehabilitation) Combined practice group (yoga and rehabilitation)

Main outcome variables

pre-inflammatory factors (ptx-3, IL-6, CRP) and depression levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181224042084N1**

Registration date: **2019-01-15, 1397/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-15, 1397/10/25**

Update count: **0**

Registration date

2019-01-15, 1397/10/25

Registrant information

Name

Zahra Fathollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4407 4244

Email address

mahsafathollahi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-01, 1397/04/10

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

The effect of long-term combination training (rehabilitation-yoga) on some of the pre-inflammatory factors and depression levels in coronary artery disease patients after surgery.

Public title

The effect of yoga combinations and cardiac rehabilitation in CABG patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

CABG surgery patients Between 45 to 75 years old
Discharge phase Sex:male Up to 35% ejection fraction
Use of the same drugs at the time of the study

Exclusion criteria:

Not having more than 100 km distance from the Rehab center
No history of heart surgery
No motor and orthopedic problems

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize at this stage, the names of people in the envelope and the codes defined on them by one person (other than the administrators) in two groups of control (rehearsal practice) and experimental group (combined practice) randomly Are divided

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee on Biomedical Research Science and Research Unit, Islamic Azad University

Street address

Islamic Azad University, Science and Research Branch, Hesarak, End of Ashrafi Isfahani, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1477893855

Approval date

2018-03-04, 1396/12/13

Ethics committee reference number

IR.IAU.SRB.REC.1396.98

Health conditions studied**1****Description of health condition studied**

CABG surgery patients

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes**1****Description**

change in pre inflammatory factors

Timepoint

24 hours before the intervention begins and 24 hours after the end of the

Method of measurement

collecting 10 CC of Blood samples during rest in the fasting state

2**Description**

Depression levels

Timepoint

24 hours before the intervention begins and 24 hours after the end of the training period

Method of measurement

Completing SCL-90 questionnaire

Secondary outcomes**1****Description**

PTX-3-Blood Pre -inflammatory factors

Timepoint

24 hours before the intervention begins and 24 hours after the end of the training period

Method of measurement

10 CC of Blood samples are collected at rest in the fasting state

2**Description**

(CRP)Blood Pre -inflammatory factors

Timepoint

24 hours before the intervention begins and 24 hours after the end of the training period

Method of measurement

10 CC of Blood samples are collected at rest in the fasting state

3**Description**

IL-6(Blood Pre -inflammatory factors)

Timepoint

24 hours before the intervention begins and 24 hours after the end of the training period

Method of measurement

10 CC of Blood samples are collected at rest in the fasting state

Intervention groups**1****Description**

Control group:8 weeks/ per weeks three times about 1 hour Routine Cardiac rehabilitation program Includes 30 minutes walking on treadmill, 20-30 minutes working with foot and hand bicycle With an intensity equal to 65-80% of maximum heart rate depends on patients tolerance.

Category

Rehabilitation

2**Description**

Intervention group: Yoga Combined Practice and Cardiac Rehabilitation, In the middle of a meeting, 8 weeks/ per weeks three times about 1 hour (A yoga practice session and a routine rehearsal exercise session)

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Shahid Rajaei Heart Hospital

Full name of responsible person

Zahra Fathollahi

Street address

End of Hashemi Rafsanjani Highway

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1995614331

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fakhari2013fatemeh@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Rajaei Hospital

Full name of responsible person

Sara Lotfian

Street address

End of Hashemi Rafsanjani High way

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Tehran

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lotfiansara@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Rajaei Hospital

Proportion provided by this source

50

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**

Islamic Azad University

Full name of responsible person

Zahra Fathollahi

Position

Ph.D. Student, Azad University of Science and Research, Tehran, Iran

Latest degree

Master

Other areas of specialty/work

Sport Physiology of cardiovascular and respiration

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable