

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect Of Long Term Combined Cardiac Rehabilitation And Yoga Training On Electrocardiogram Changes And Cardiac Autonomic System In Coronary Artery Patients After Surgery

Protocol summary

Study aim

The effect of long-term combined training, rehabilitation and yoga on electrocardiographic changes and cardiac autonomic system in post-operative coronary artery disease patients.

Design

Samples were performed from coronary artery bypass grafting patients in the Shahid Rajaee Cardiology Center, and they were cleared in Phase 2, were randomly selected. Patients are randomly assigned into two groups of rehab and yoga-rehabilitation. In order to blindness at this stage, the names of people in the envelope and the codes defined on them by one person (other than the anchors) in two groups of control (rehabilitation exercise (n=15)) and experimental group (combined exercise (n=15)) are randomly divided be.

Settings and conduct

The control group and the combined exercises group should be present at the rehabilitation department of Tehran's Shahid Rajaee Cardiology Hospital during the course of the project (8 weeks), weekly three sessions for 1 hour. 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 who have coronary artery bypass grafts and male gender. - Do not use drugs or cigarettes. - Non-use of unauthorized drugs and the use of similar drugs at the time of the study - Having no history of heart attacks or heart failure - Lack of movement disorders that prevent exercise in rehab. - Lack of space more than 100 km from the center of rehab - absence of ejection fraction less than 35% - oral health control due to salivary measurements

Intervention groups

Control group (cardiac rehab) Combined exercise training group (yoga and rehab)

Main outcome variables

Electrocardiogram changes, Autonomic changes in the heart (HRV, salivary cortisol & alpha amylase)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180728040615N1**

Registration date: **2018-12-14, 1397/09/23**

Registration timing: **retrospective**

Last update: **2018-12-14, 1397/09/23**

Update count: **0**

Registration date

2018-12-14, 1397/09/23

Registrant information

Name

Fatemeh Fakhariad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4486 5223

Email address

phdfakhari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-30, 1397/02/10

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

2018-06-21, 1397/03/31

Actual recruitment end date

2018-08-28, 1397/06/06

Trial completion date

2018-10-17, 1397/07/25

Scientific title

Effect Of Long Term Combined Cardiac Rehabilitation And Yoga Training On Electrocardiogram Changes And Cardiac Autonomic System In Coronary Artery Patients After Surgery

Public title

Effect of combined yoga and rehabilitation in CABG patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who underwent coronary artery bypass graft surgery in Shahid Rajai's Heart Hospital 45-75 years old. At least one month have passed since surgery

Exclusion criteria:

Having a history of heart attacks, heart surgery or congestive heart failure Major motor disturbances Having more than 100 km distance from Shahid Rajaee Cardiac Rehabilitation Center in Tehran Having ejection fraction at least 35% Drug use and smoking

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**

Actual sample size reached: **20**

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 (except the administrators) in two groups of control (rehabilitation) and experimental group (combined training) 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 Branch, Islamic Azad University

Street address

Islamic Azad University of science & Reaserch branch, Tehran, Iran. Hesarak, Ashrafi ESfehani,

City

Tehran

Province

Tehran

Postal code

۱۴۷۷۸۹۳۸۵۵

Approval date

2018-03-04, 1396/12/13

Ethics committee reference number

IR.IAU.SRB.REC.1396.97

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

coronary artery bypass grafting

ICD-10 code

I25.7

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

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

Electerocardiographic changes

Timepoint

48 hours before the intervention begins and 48 hours after the end of the training period

Method of measurement

It is measured by an electrocardiogram device in the Shahid Rajaie Cardiology and Cardiology Hospital.

2**Description**

cardiac autonomic changes

Timepoint

48 hours before the intervention begins and 48 hours after the end of the training period

Method of measurement

Measurement of heart rate variability with existing Holter device in Shahid Rajaee Heart Hospital, measurement of salivary alpha amylase and cortisol at rest

Secondary outcomes

1

Description

heart rate variability(HRV)

Timepoint

48 hours before the training period and 48 hours after the training period

Method of measurement

Holter monitoring 24 hours

2

Description

Salivary Cortisol

Timepoint

48 hours before and after of training period

Method of measurement

Take saliva in the form of fasting at rest in saliva special tubes

3

Description

Salivary amylase alpha

Timepoint

At the beginning of the study and 48 hours before the intervention, and 48 hours after the end of the intervention,

Method of measurement

Take saliva in the form of fasting at rest in saliva special tubes

Intervention groups

1

Description

Control group: cardiac rehabilitation training, Patients in this group have routine hospital rehab sessions that lasts eight weeks of training, three sessions per week for one hour, including aerobic exercises on a treadmill for 30 minutes, 20-30 minutes for arm and leg cycles.

Category

Rehabilitation

2

Description

Intervention group: combined training of yoga and cardiac rehabilitation, In this type of exercises, patients have three sessions each week for for eight weeks, for 1 hour per session. It performs a session of yoga practice and next session a routine rehearsal training .

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee Heart Hospital

Full name of responsible person

Fatemeh Fakhari Rad

Street address

Hashemi Rafsanjani Hwy, Shahid Rajaee Hospital

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fakhari2013fatemeh@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Rajaee Heart Hospital

Full name of responsible person

Sara Lotfian

Street address

At The End Of Hashemi Rafsanjani High Way, Shahid Rajaee Heart Hospital

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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

Shahid Rajaee Heart 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

Fatemeh Fakhari Rad

Position

PHD Student Of Science & Reaserch Branch, Eslamic Azad University ,Tehran , Iran.

Latest degree

Master

Other areas of specialty/work

Physiology

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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