

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparison of the effects of continuous and short and long-term high interval training on rehabilitation of cardiovascular patients

#### Protocol summary

##### Summary

The purpose of this study will be investigation and comparison of different exercise training program on rehabilitation of cardiac disease with coronary artery bypass graft operation (CABG). The study design will be base on double blind. Ninety patient post CABG surgery will be divided equally into three groups: continuous and periodic exercises 1 and 2. Inclusion criteria: left ventricular ejection fraction  $\geq 50\%$ , sinus rhythm and 4-16 week after CABG surgery; Exclusion criteria: peripheral vascular disease, valvular disease, atrial or ventricular premature beats, conduction defects, orthopedic or neurological limitation associated with exercise cessation of drug use during the study. Protocol of continues training ( 3 session per week, 45 minutes at 70 % reserve heart rate), high intensity interval -1 ( 5  $\times$ 4 minutes at 85-90% reserve heart rate and 3 minute interval at 60-70% reserve heart rate) and high intensity interval -2 ( 9 $\times$ 2 minutes at 85-90% reserve heart rate and 2 minute interval at 60-70% reserve heart rate) will be undertaken for 6 weeks. Indicators of rest and maximal heart rate, heart rate variability and quality of life will be measured before and after the 6 week training program.

#### General information

##### Acronym

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##### IRCT registration information

IRCT registration number: **IRCT2015070123002N1**  
Registration date: **2016-01-09, 1394/10/19**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-01-09, 1394/10/19

#### Registrant information

##### Name

Alireza Ghardashi Afousi

##### Name of organization / entity

University of Tehran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8201 5031

##### Email address

ghardashi.a@ut.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Investigator

#### Expected recruitment start date

2015-11-22, 1394/09/01

#### Expected recruitment end date

2016-02-20, 1394/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effects of continuous and short and long-term high interval training on rehabilitation of cardiovascular patients

#### Public title

Clinical trial: Comparison of the effects of continuous and short and long-term high interval training on rehabilitation of cardiovascular patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: sinus rhythm, left ventricular ejection fraction  $\geq 50\%$  and 4- 16 week after coronary artery

bypass graft surgery; Exclusion criteria: coexisting valvular and/or peripheral vascular diseases, frequent atrial or ventricular premature beats, conduction defects, pericarditis, peripheral neuropathy, orthopedic or neurological limitations, cessation of drug use during the study

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 90

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

After baseline measurement, using the online randomization (<http://www.graphpad.com/quickcalcs/index.cfm>) subjects randomized and stratified to 3 groups (high interval intensity training-1, 2 and continuous training)

**Secondary Ids**

empty

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

Ethic comitee of Baqiyatallah University of Medical Sciences

**Street address**

Exercise Physiology Research Center, Research, Baqiyatallah University of Medical Sciences, Alley Nosrati, St Sheikh Bahai, Mulla sadra, Vanak Square, Tehran

**City**

Tehran

**Postal code****Approval date**

2015-11-22, 1394/09/01

**Ethics committee reference number**

IR.BMSU.REC.1394.40

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

Cardiovascular disease post coronary artery bypass graft

**ICD-10 code**

I23

**ICD-10 code description**

Myocardial infarction specified as acute or with a stated duration of 4 weeks (28 days) or less from onset

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

Resting heart rate

**Timepoint**

Before and after 6 week

**Method of measurement**

Polar beat heart rate

**2****Description**

Ejection fraction

**Timepoint**

Before and after 6 week intervention

**Method of measurement**

2 dimensional echocardiography

**3****Description**

Maximal heart rate

**Timepoint**

Before and after 6 week intervention

**Method of measurement**

Polar beat heart rate

**4****Description**

cardiac output

**Timepoint**

Before and after 6 week intervention

**Method of measurement**

2 dimensional echocardiography

**5****Description**

Rate product pressure

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

2 dimensional echocardiography

**6****Description**

End-systolic diameter

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

2 dimensional echocardiography

**7**

**Description**

End-diastolic diameter

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

2 dimensional echocardiography

**8**

**Description**

Stroke volume

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

2 dimensional echocardiography

**9**

**Description**

Heart rate variability

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

Cardiac holter monitoring

**10**

**Description**

Quality of life

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

The World Health Organization Quality of Life Questionnaire

**11**

**Description**

Plasma glucose level

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

Enzymatic

**12**

**Description**

Serum triglycerides

**Timepoint**

Before and after 6 week intervention

**Method of measurement**

Photometry

**13**

**Description**

Serum cholesterol

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

Photometry

**14**

**Description**

Serum LDL

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

Photometry

**15**

**Description**

Serum HDL

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

Photometry

**16**

**Description**

Blood pressure

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

Barometer

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group 1: moderate intensity continuous exercise (MICE) consist of 45 minutes at 70 % heart rate reserve, 3 session per week for 6 week. Warm- up and cool- down for patients at the start and end of each training session is at 50-55% heart rate reserve.

**Category**

Rehabilitation

**2**

**Description**

Intervention group 2: high intensity interval training-1 consist of: warm up 5 minutes at 50-55% heart rate reserve, and 5x4 minutes at 85-90% heart rate reserve and 3 minutes active period interval at 60-70% heart rate reserve, and the end of session of training cool down is 5 minutes at 50-55% heart rate reserve.

**Category**

Rehabilitation

**3**

**Description**

Intervention group 3 : high intensity interval training-2

consist of: warm up 5 minutes at 50-55% heart rate reserve, and 9×2 minutes at 85-90% heart rate reserve and 3 minutes active period interval at 60-70% heart rate reserve, and the end of session of training cool down is 5 minutes at 50-55% heart rate reserve.

**Category**

Rehabilitation

**4****Description**

Control group: No any exercise training program and maintain daily activities

**Category**

Rehabilitation

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

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

bahram pishgoo MD, Mohammad Taghi Holisaz MD

**Street address****City**

Tehran

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

Investigator

**Full name of responsible person**

Alireza Ghardashi Afousi

**Street address**

Exercise physiology research center, research, University of Medical Sciences of Baqiyatallah, Alley shahid nosrati, Street Shikh bahaei, Molla sadra, Vanak Square

**City**

Tehran

**Grant name**

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**Grant code / Reference number**

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**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Investigator

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Alireza Ghardashi Afousi

**Position**

Ph.D candidate

**Other areas of specialty/work****Street address**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*