Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Effects of cardiac rehabilitation on C-reactive protein, neutrophil-to-lymphocyte, and platelet-to-lymphocyte ratio in unstable ischemic heart disease patients following percutaneous coronary intervention: A randomized clinical trial

Protocol summary

Study aim

Evaluating inflammatory markers (including c reactive protein (CRP) , neutrophil to lymphocyte ratio (NLR) , and platelet to lymphocyte ration (PLR)) after cardiac rehabilitation (CR) in patient with unstable ischemic heart disease (UIHD) who underwent successful percutaneous coronary intervention (PCI).

Design

Single center , two groups :the control (n=40) and the CR (cardiac rehabilitation , n =80) group, permuted block stratified randomization, double arm randomized control trial, parallel design, randomization with computer software. Due to the nature of the intervention it was not possible to blind either the patients or the care givers.

Settings and conduct

The study was performed at Tehran Heart Center Hospital. Blood sample is taken form patients before discharge from the hospital (patients were hospitalized due to PCI) and the variables of interest were measured. 12 weeks later, during which time the intervention group underwent cardiac rehabilitation and routine care after PCI and the control group received only routine care, blood samples are taken again. The person taking the samples and entering the information and the person performing the analysis was blind to the group of patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria : all >18 years patients with unstable ischemic heart disease (UIHD) with negative cardiac enzymes who had undergone successful PCI . Exclusion: Patients aged >70 or with uncontrolled diseases or previous cardiac interventions or other concomitant cardiac diseases

Intervention groups

The cardiac rehabilitation program included once-a-week supervised aerobic exercise sessions and educational sessions for 12 weeks. In the latter, patients were ducated about various lifestyle modifications.

Main outcome variables

Blood inflammatory markers after 12 weeks of cardiac rehabilitation :

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210827052304N2**
Registration date: **2022-12-03, 1401/09/12**
Registration timing: **retrospective**

Last update: **2022-12-03, 1401/09/12**
Update count: **0**

Registration date

2022-12-03, 1401/09/12

Registrant information

Name

Mana Jameie

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-01, 1396/10/11

Expected recruitment end date

2020-09-01, 1399/06/11

Actual recruitment start date

2018-01-01, 1396/10/11

Actual recruitment end date

2020-09-01, 1399/06/11

Trial completion date

2020-12-01, 1399/09/11

Scientific title

Effects of cardiac rehabilitation on C-reactive protein, neutrophil-to-lymphocyte, and platelet-to-lymphocyte ratio in unstable ischemic heart disease patients following percutaneous coronary intervention: A randomized clinical trial

Public title

Effect of cardiac rehabilitation on inflammatory markers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All > 18 years patients with unstable ischemic heart disease (UIHD) with negative enzymes who had undergone successful percutaneous coronary intervention (PCI) Informed consent

Exclusion criteria:

Age > 70 years History of dysrhythmia History of decompensated heart failure History of coronary artery bypass graft (CABG) History of myocardial infarction Uncontrolled hypertension Uncontrolled diabetes mellitus, Physical disability History of respiratory dysfunction History of cerebrovascular diseases History of severe valvular heart diseases History of any known inflammatory diseases other than atherosclerosis Ongoing clinical infection Planned surgery within the next four months

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were allocated in the two groups by permuted stratified randomization technique (ratio 2:1 , for each control patient we enrolled 2 cases in the intervention group) with random block sizes of 3,6,12,6, and 18. Unit of randomization was individuals. The computer software (Block stratified randomization windows version 6 copyright 2010 by Steven Patntadosi) was used for randomization. Given the single-centre nature of the study, an intra-hospital web-based registry software was designed by the IT specialists of the hospital and the generated random sequence were recorded in it ,therefore allocation concealment (random sequence concealment) was carried out.

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

Research Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences Office of Vice-Chancellor for Global Strategies and International Affairs, Number 21, Dameshgh St., Vali-e Asr Ave., Tehran 1416753955 Iran

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Approval date

2019-12-21, 1398/09/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.514

Health conditions studied

1

Description of health condition studied

Evaluating inflammatory markers in patients with unstable ischemic heart diseases after cardiac rehabilitation

ICD-10 code

I20.0

ICD-10 code description

Unstable angina

Primary outcomes

1

Description

High sensitivity CRP

Timepoint

The mentioned factor were taken at Baseline mode (ie before the discharge of patients admitted for PCI). After

this time, patients in the intervention group received 12 week cardiac rehabilitation and the control group received only routine care. At the end of 12 weeks, blood samples were taken again from both groups of patients.

Method of measurement

hs-CRP : hs-CRP kit by ROCHE company

2

Description

Platelet to lymphocyte ratio

Timepoint

The mentioned factor were taken at Baseline mode (ie before the discharge of patients admitted for PCI). After this time, patients in the intervention group received 12 week cardiac rehabilitations and the control group received only routine care. At the end of 12 weeks, blood samples were taken again from both groups of patients.

Method of measurement

PLR : platelet count(per cubic millimeter of blood) divided by lymphocyte count (per cubic millimeter of blood) . Cell count was performed using SYSMEX cell counter

3

Description

Neutrophil to lymphocyte ratio

Timepoint

The mentioned factor were taken at Baseline mode (ie before the discharge of patients admitted for PCI). After this time, patients in the intervention group received 12 week cardiac rehabilitations and the control group received only routine care. At the end of 12 weeks, blood samples were taken again from both groups of patients.

Method of measurement

NLR : neutrophil count(per cubic millimeter of blood) divided by lymphocyte count (per cubic millimeter of blood) - Cell count was performed using SYSMEX cell counter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: , Patients in the intervention group underwent a 12-week cardiac rehabilitation. The cardiac rehabilitation program included once-a-week supervised aerobic exercise session and once-a-week educational sessions for 12 weeks which started immediately after discharge. In the former, patients warmed up for 10 minutes, did isometric movements for 30 minutes, and then coolled down for 10 minutes. Patients' exercise intensity gradually increased from 50 to 80% of the heart rate reserve. In the latter, patients were educated about various lifestyle modifications: routine checking of vital signs, losing extra weight, quitting smoking, consuming appropriate fresh fruit, vegetables, fibers, and cereals, reducing alcohol, salt, and fat intake, and avoiding extreme heat and cold preventing heavy activities. In addition, patients learnent how to identify and tackle everyday sources of stress. They also received the routine care after PCI including including dual platelet inhibition, acetylsalicylic acid (Pars Darou company), and clopidogrel (Abidi company) in addition to statins (Sobhan Darou company), in accordance with current guidelines

Category

Rehabilitation

2

Description

Control group: Patients in this group only received the routine care after PCI including dual platelet inhibition, acetylsalicylic acid, and clopidogrel in addition to statins, in accordance with current guidelines

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran heart center hospital

Full name of responsible person
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Sponsors / Funding sources

1

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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
Tehran 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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

No - There is not a plan to make this available