

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of "Enhanced External Counterpulsation Combined with Cardiac Rehabilitation" and "only Cardiac Rehabilitation" on Clinical Parameters and plasma Nitric oxide, Endoteline and High sensitive CRP in the Patients with Coronar artery Diseases

Protocol summary

Summary

The aim of this study is to compare the effects of "cardiac rehabilitation" and "cardiac rehabilitation combined with EECP" on patients with ischemic heart disease according to the biochemical parameters (plasma levels of nitric oxide, endothelin-1 and High sensitive CRP) as a primary outcome and clinical parameters (Canadian Cardiovascular Society Angina scale, quality of life questionnaire SF36) as secondary outcomes. A total of 40 cases of ischemic heart disease, which is documented by angiography, perfusion scan, ECG or exercise stress test, with at least ejection fraction of 30% and age more than 30 years old will be enrolled. The patients are randomly assigned into 2 groups: Group A receive only 20-session cardiac rehabilitation, based on CR-2 protocol includes a 10 minutes warm up, 20 minutes walking on treadmill, cycling on stationary bike, and finally 5 minutes of relaxation and cool down take place. Group B receive with cardiac rehabilitation combined with 35 sessions of EECP that each session lasting one hour. Before treatment and at the end of the study, HSCR, ET1, and NO are checked. And in the group B, prior to receiving EECP, HSCR, ET1, and NO are rechecked. CCS Angina Scale and the quality of life questionnaire SF36 will be completed by the patients at the beginning and at end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111024422N3**
Registration date: **2011-11-21, 1390/08/30**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-11-21, 1390/08/30

Registrant information

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Seyed Kazem Shakouri

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

vice-chancellor Of Research, Tabriz University of Medical Science

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of "Enhanced External Counterpulsation Combined with Cardiac Rehabilitation" and "only Cardiac Rehabilitation" on Clinical Parameters and plasma Nitric oxide, Endoteline and High sensitive CRP in the Patients

Public title

Comparison of the effects of "EECP Combined with Cardiac Rehabilitation" and "only Cardiac Rehabilitation" on the treatment of ischemic heart disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients after myocardial infarction, age over 30 years old, ischemic heart disease which is documented by at least one of the followings: angiography, Perfusion scan, ECG, exercise Test, EF \geq 30
Exclusion criteria: Arrhythmias that will lead to impaired performance, susceptibility to bleeding, Active thrombophlebitis, proven aortic aneurysms that require to surgery, pregnancy, patients with significant valvular heart disease (Severe AI-severe AS - severe MS), using of nitrocalcine

Age

From **30 years** old to **149 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Vice-chancellor for research, Tabriz University of Medical Sciences

Street address

Research center, No 2 central building, Tabriz University of Medical Sciences

City

Tabriz

Postal code**Approval date**

2011-10-19, 1390/07/27

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Ischemic heart disease

ICD-10 code

I20-I25

ICD-10 code description

Ischemic heart disease

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

level of blood hsCRP

Timepoint

before beginning and at the end of study for all patients,also for group B before EECP

Method of measurement

using the kit of hsCRP(mg/lit)

2**Description**

level of blood Nitric oxide

Timepoint

before beginning and at the end of study for all patients,also for group B before EECP

Method of measurement

using the kit of Nitric oxide (umol/lit)

3**Description**

level of blood Endotelin-1

Timepoint

before beginning and at the end of study for all patients ,also for group B before EECP

Method of measurement

using the kit of Endotelin-1(pg/lit)

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

clinical parameters

Timepoint

before beginning and at the end of study for all patients

Method of measurement

quality of life questionnaire sf36, Canadian Cardiovascular Society Angina scale

Intervention groups

1

Description

Group A: only 20-sessions cardiac rehabilitation, based on CR-2 protocol includes a 10 minutes warm up, 20 minutes walking on treadmill ,cycling on stationary bike, and finally 5 minutes of relaxation and cool down

Category

Rehabilitation

2

Description

Group B: cardiac rehabilitation combined with 35 sessions of EECF that each session lasting one hour

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Shaheed Madani hospital

Full name of responsible person

Dr seyed kazem shakouri

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice-chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Rashidi

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Research center, No 2 central building, Tabriz University of Medical Sciences

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

vice-chancellor for Research, Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Seyyed Kazem Shakouri

Position

Physical medicine and rehabilitation professional, MD

Other areas of specialty/work

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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