

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of combined selenium and Coenzyme Q10 on left ventricular function and functional capacity in patients with heart failure (left ventricular dysfunction)

Protocol summary

Summary

According to Low cardiac contents of selenium and coenzyme Q10 in patients with heart failure; The aim of this study is to evaluate the vital relationship between two substances to obtain optimal function of the myocardium. Inclusion criteria are male and female patients with ischemic or nonischemic heart failure with LVEF less than 50% and NYHA CLASS 2, 3 white no change in their previous medical treatment and no revascularization Procedure during the last month. Exclusion criteria are the patient whom experienced acute coronary syndrome in the Course of the study or have any change in medical treatment or have any revascularization Procedure during the study.the patient white severs renal or hepatic or respiratory failure are excluded.3 month randomized double-blind placebo-controlled trial among Iranian citizens aged 30 to 85 will perform in 64 participants given combined supplementation of 200mcg selenium and 90mg coenzyme Q10 per day or a placebo. Clinical examinations NYHA functional capacity classification and echocardiography white simpson method will perform before and after intervention. Participants were monitored every 1th month throughout the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020512371N1**
Registration date: **2013-10-28, 1392/08/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-28, 1392/08/06

Registrant information

Name

Parvin Bahrami

Name of organization / entity

Isfahan University of Medical Sciences

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p_bahrami.2010@yahoo.com

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences and CO Q10 is Sponsored by eksir Company

Expected recruitment start date

2013-10-07, 1392/07/15

Expected recruitment end date

2013-11-06, 1392/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of combined selenium and Coenzyme Q10 on left ventricular function and functional capacity in patients with heart failure (left ventricular dysfunction)

Public title

Effect of combined selenium and Coenzyme Q10 on heart failure treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male and female with ischemic and nonischemic heart failure; aged between 30 to 85 years old; LVEF less than 50% (with simpson method); NYHA CLASS 2,3; stability for 1month with no change in dose and kind of drugs in at least one month prior. Exclusion criteria: ACS or Revascularization procedure in 1month before or during study; heart failure with killip class 3, 4; active Myocarditis and pericarditis; uncontrolled HTN; severe renal dysfunction (GFR less than 30%); pulmonary dysfunction(PCO2 more than 45 and Po2 less than 60); liver dysfunction(CHILD 2,3).

Age

From **35 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Azadi Square,
Isfahan

City

Isfahan

Postal code**Approval date**

2012-08-22, 1391/06/01

Ethics committee reference number

392080

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

Heart failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart failure

2**Description of health condition studied**

Heart failure

ICD-10 code

I50.1

ICD-10 code description

Left ventricular failure

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

EF (Simpson)

Timepoint

before intervention- after 3 month intervention

Method of measurement

echocardiography

2**Description**

functional class with NYHA CLASS

Timepoint

BEFORE INTERVENTION-3MONTH LATER

Method of measurement

questionnaire

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

Gastrointestinal symptoms/diarrhea

Timepoint

at the end of each month

Method of measurement

interview

2**Description**

echocardiography parameter (LVEF Mmode, EDD, ESD)

Timepoint

after and before intervention

Method of measurement

echocardiography

3**Description**

skin rash

Timepoint

each month

Method of measurement

interview

Intervention groups

1

Description

intervention group: co Q10 30 mg TID selenium 200 mcg OD

Category

Treatment - Drugs

2

Description

control group: 2kind of Placebo as form of co q10 and selenium

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Cardiovascular disease Dr Mohammad Grakyaraghi

Full name of responsible person

Dr Mohammad Grakyaraghi

Street address

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Isfahan

2

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Dr Parvin Bahrami

Street address

Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Medical Research Department of Isfahan University

Full name of responsible person

Dr Mirali Mohammad Sabz Ghabaii

Street address

Azadi Square, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Medical Research Department of Isfahan University

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Exir Pharmaceutical Companies

Full name of responsible person

Dr Noshin Chitsaz

Street address

Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Exir Pharmaceutical Companies

Proportion provided by this source

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

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Position

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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