

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of the effects of complementary creatine monohydrate and exercise on inflammatory markers and endothelial functions among patients with cardiac failure in comparison with control group

Protocol summary

Summary

This study aims to evaluate the effects of complementary creatine monohydrate and regular exercise on inflammatory markers and endothelial function among patients with chronic cardiac failure. This study is performed by an interventional double blind investigation among 100 patients who showed cardiac symptoms and LVEF less than 45% and were categorised among those with functional class equal or less than III according to NYHA classification. After completion of consent form, patients were divided into intervention and control groups randomly. Intervention group receives creatine monohydrate supplement as much as 5 grams dissolved in water daily and regular exercise for 12 weeks and control group receive maltodextrin 5gr/daily for 12 weeks. For measuring different markers including P-selectine, ICAM-1, IL-6, hs-CRP and VCAM-1 and comparison the results between interventional and control groups, patients are taken blood samples at the start and end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061718128N1**

Registration date: **2014-08-29, 1393/06/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-29, 1393/06/07

Registrant information

Name

Farajollah Hemati

Name of organization / entity

Ilam University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 84 1334 3456

Email address

hemati-f@medilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Researches and Technical information,
Ilam University of Medical Sciences

Expected recruitment start date

2014-05-31, 1393/03/10

Expected recruitment end date

2014-07-11, 1393/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of complementary creatine monohydrate and exercise on inflammatory markers and endothelial functions among patients with cardiac failure in comparison with control group

Public title

The effects of creatine monohydrate and exercise on congestive heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Including criteria: being outpatient; LVEF \leq 45%;
Functional class \geq III NYHA. Excluding criteria:

Uncontrolled arrhythmia; persistent and severe chest pain; glucosamide or mineral vitamin consumption; known renal failure; arterial abnormalities; sensitive to Sulfur Components; not regularly participation in the study performances.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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**

Ilam University of Medical Sciences

Street address

Ethics committee, Banganjab, Ilam University of Medical Sciences

City

Ilam

Postal code**Approval date**

2014-05-31, 1393/03/10

Ethics committee reference number

EC/93/H/233

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

Cardiac failure

ICD-10 code

I50.9

ICD-10 code description

Heart failure, unspecified

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

High sensitive C reactive protein

Timepoint

start and end of intervention

Method of measurement

serum level of marker using Bender Medsystem kits

2**Description**

IL6

Timepoint

start and end of intervention

Method of measurement

serum level of marker using Bender Medsystem kits

3**Description**

P-selection

Timepoint

start and end of intervention

Method of measurement

serum level of marker using Biosource International Kit

4**Description**

ICAM-1

Timepoint

start and end of intervention

Method of measurement

serum level of marker using Biosource International Kit

5**Description**

VCAM-1

Timepoint

start and end of intervention

Method of measurement

serum level of marker using Biosource International Kit

Secondary outcomes

empty

Intervention groups**1****Description**

Interventional group: Receive creatine monohydrate complementary and regular exercises until 12 weeks

Category

Rehabilitation

2

Description

Control group receive maltodextrin 5gr/daily without exercise until 12 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sport and Physical Medicine Clinic

Full name of responsible person

Dr Farajollah Hemati

Street address

Sport and Physical Medicine Clinic, 22 Bahman Square, Ilam city

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr Morovat Taherikalani

Street address

Vice Chancellor for researches and Technology, Banganjab, Ilam University of Medical Sciences

City

Ilam

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ilam 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

Ilam University of Medical Sciences

Full name of responsible person

Dr Farajollah Hemati

Position

Asistant prof., specialist in sport medicine

Other areas of specialty/work

Street address

Dept. of Internal Medicine, Faculty of Medicine, Ilam University of Medical Sciences

City

Ilam

Postal code

Phone

+98 84 1223 5738

Fax

Email

hemati-f@medilam.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr Khairollah Asadollahi

Position

Associate prof. Epidemiologist

Other areas of specialty/work

Street address

Dept. Epidemiology, Banganjab, Faculty of Medicine, Ilam University of Medical Sciences

City

Ilam

Postal code

Phone

+98 84 1222 7126

Fax

Email

Masoud_1241@yahoo.co.uk

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Dr Solimannezhad Kouresh

Position

Cardiologist

Other areas of specialty/work

Street address

City

Postal code

Phone

0098

Fax

Email

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