

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 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

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#### 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

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+98 84 1222 7126

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#### 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*