

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### The effect of vitamin D3 supplementation on serum levels of B type natriuretic peptide , tumor necrosis factor alpha , high sensitivity c-reactive protein and 6 minute walk distance test in stage III systolic heart failure patients with vitamin D deficiency

#### Protocol summary

##### Summary

This study will be performed within 2 months to investigate the effect of vitamin D3 supplementation on serum levels of B type natriuretic peptide, tumor necrosis factor alpha, high sensitivity C- reactive protein and 6 minute walk distance test in patients with stage III systolic heart failure with vitamin D deficiency. This study is a controlled, randomized, double-blinded clinical trial and Block Randomization will be used. The study population includes men and women with heart failure and vitamin D deficiency referred to Urmia Taleghani hospital. Subjects with stage III of NYHA, vitamin D deficiency and ejection fraction less than 50% will be studied. 44 patients of them will randomly divide into intervention and placebo groups. The intervention group will receive vitamin D3 supplement tablets and the placebo group will receive size-color matched placebo tablets. Brain natriuretic peptide, tumor necrosis factor alpha, High sensitivity C-reactive protein and vitamin D levels will be measured through blood sampling before and after the intervention and will be analyzed. Also 6 minute walk distance test will be checked in two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016102113678N13**  
Registration date: **2017-03-02, 1395/12/12**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-03-02, 1395/12/12

#### Registrant information

##### Name

Saeed Ghavamzadeh

##### Name of organization / entity

Urmia University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 1278 0803

##### Email address

ghavamzadeh\_s@umsu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Urmia University of Medical Sciences

#### Expected recruitment start date

2016-09-22, 1395/07/01

#### Expected recruitment end date

2016-12-20, 1395/09/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of vitamin D3 supplementation on serum levels of B type natriuretic peptide , tumor necrosis factor alpha , high sensitivity c-reactive protein and 6 minute walk distance test in stage III systolic heart failure patients with vitamin D deficiency

#### Public title

The effect of vitamin D in the treatment of heart failure

#### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria : class 3 of the New York Heart Association Classification(NYHA); ejection fraction less than 50% ; treated with heart failure medications in the last 3 months ; the level of vitamin D less than 20 ng/ml. Exclusion criteria : vitamin D reception in the last 2 months ; acute gastrointestinal problems ;using interacting drugs with the homeostasis of vitamin D such as Corticosteroids , Thyroxine , anti-epileptic drugs, Tetracycline, Ketoconazole, Cholestyramine, Phenobarbital and Phenytoin ; bone fractures ; continuous consumption of cigarettes; kidney disease ; malignancies ; need to change the type and amount of drugs during the study

### **Age**

No age limit

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **44**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Other

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Urmia University of Medical Sciences

##### **Street address**

Orjhans Street, Resalat Blvd, Urmia , Iran

##### **City**

Urmia

##### **Postal code**

5714783734

#### **Approval date**

2016-07-31, 1395/05/10

#### **Ethics committee reference number**

IRUMSU.REC.1395

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

heart failure

#### **ICD-10 code**

I50.9

#### **ICD-10 code description**

Cardiac, heart or myocardial failure NOS

## **Primary outcomes**

### **1**

#### **Description**

B type natriuretic peptide

#### **Timepoint**

before and after intervention

#### **Method of measurement**

ELISA

### **2**

#### **Description**

high sensitivity C-reactive protein

#### **Timepoint**

before and after intervention

#### **Method of measurement**

ELISA

### **3**

#### **Description**

tumor necrosis factor alpha

#### **Timepoint**

before and after intervention

#### **Method of measurement**

ELISA

### **4**

#### **Description**

vitamin D

#### **Timepoint**

before and after intervention

#### **Method of measurement**

ELISA

### **5**

#### **Description**

6 minute walk distance test

#### **Timepoint**

before and after intervention

#### **Method of measurement**

walking distance (meter)

## **Secondary outcomes**

## 1

### **Description**

systolic blood pressure

### **Timepoint**

before and after intervention

### **Method of measurement**

manometer

## 2

### **Description**

diastolic blood pressure

### **Timepoint**

before and after intervention

### **Method of measurement**

manometer

## 3

### **Description**

weight

### **Timepoint**

before and after intervention

### **Method of measurement**

scale

## 4

### **Description**

body mass index

### **Timepoint**

before and after intervention

### **Method of measurement**

with BMI formula

## **Intervention groups**

## 1

### **Description**

Viatmin D3 tablet (50000 International Unit) once a week , for two months

### **Category**

Treatment - Drugs

## 2

### **Description**

placebo tablet , once a week , for two months

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Taleghani Hospital

#### **Full name of responsible person**

Fahimeh Hosseinzade

#### **Street address**

West Azarbaijan,Urmia,Kashani st,Taleghani hospital

#### **City**

Urmia

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Vice Chancellor for research of Urmia University of Medical Sciences

#### **Full name of responsible person**

Dr Iraj Mohebbi

#### **Street address**

Orjhans Street, Resalat Blvd, Urmia , Iran

#### **City**

Urmia

#### **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 of Urmia 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**

## **Person responsible for scientific inquiries**

### **Contact**

#### **Name of organization / entity**

urmia medical science university

#### **Full name of responsible person**

Dr Saied Ghavamzadeh

#### **Position**

Associate Professor/Nutritional Sciences PhD

#### **Other areas of specialty/work**

#### **Street address**

Pardis Nazlou, 11 km of Nazlou Road,Urmia,Iran

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Urmia University of Medical Sciences

**Full name of responsible person**

Dr saied ghavamzadeh

**Position**

Associate Professor/Nutritional Sciences PhD

**Other areas of specialty/work****Street address**

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Urmia

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**Postal code****Phone**

+98 44 3278 0803

**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*