

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Sep 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

City

Urmia

Postal code

Phone

+98 44 3278 0803

Fax

Email

ghavamzadeh_s@umsu.ac.irghavamzadeh@hotmail.com

Web page address**Fax**

+98 44 1278 0801

Email

ghavamzadeh_s@umsu.ac.ir

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**

Urmia University of Medical Sciences,Nazlu Pardis,
Urmia

City

Urmia

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