Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ш 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

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Saeed Ghavamzadeh
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Urmia University of Medical Sciences
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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 ш 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
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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
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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