

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of vitamin D on improvement of left ventricular ejection fraction in patients with systolic heart failure

Protocol summary

Study aim

Determine the effect of vitamin D on left ventricular ejection fraction in patients with chronic heart failure

Design

This clinical trial study is double blinded and parallel. Patients with chronic heart failure are divided into two groups receiving vitamin D as the intervention group and placebo recipient as placebo group and are evaluated for ejection fraction before and after receiving vitamin D and placebo.

Settings and conduct

Patients referring to Ayatollah Mousavi Hospital in Zanjan who have been diagnosed with systolic heart failure, have been evaluated the left ventricular ejection fraction and cardiac failure score by using vivid echocardiography and biplane simpson prior before taking the drug. The variables studied are evaluated after 8 weeks of intervention.

Participants/Inclusion and exclusion criteria

Inclusion from study: Patients with chronic heart failure with a ejection fraction of less than 45% and greater than 20% (based on Framingham criteria, NYAH Class I, II, III) , Vitamin D levels less than 30 ng / dl, over age 40
Exclusion from study: Patients with Hypercalcemia, Osteomalacia or Corticosteroid therapy

Intervention groups

Individuals with systolic insufficiency are randomly divided into two groups of intervention group and placebo group. To a group, a placebo drug or the appearance of a capsule of vitamin D and to intervention group the natural vitamin D is given, 50,000 units and weekly for 8 weeks. Before taking the medication and 8 weeks after taking the medication, the left ventricular ejection fraction and the heart failure rating based on the NYHA ranking were calculated by vivid echocardiography with Biplane simpson method

Main outcome variables

Ejection Fraction changes, end diastolic volume, and heart failure Class

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190410043236N1**

Registration date: **2019-07-08, 1398/04/17**

Registration timing: **retrospective**

Last update: **2019-07-08, 1398/04/17**

Update count: **0**

Registration date

2019-07-08, 1398/04/17

Registrant information

Name

Hamid Khederlou

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-02, 1395/02/13

Expected recruitment end date

2017-04-15, 1396/01/26

Actual recruitment start date

2016-10-05, 1395/07/14

Actual recruitment end date

2018-07-17, 1397/04/26

Trial completion date

2018-11-17, 1397/08/26

Scientific title

Effect of vitamin D on improvement of left ventricular ejection fraction in patients with systolic heart failure

Public title

Effect of vitamin D on improvement of left ventricular ejection fraction in patients with systolic heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic heart failure with $20\% \leq EF \leq 45\%$ (based on Framingham criteria, NYAH Class I, II, III) The level of 25 (OH) Vit D is less than 30 ngr / dl Age over 40 years

Exclusion criteria:

Hypercalcemia Osteomalacia Taking corticosteroid medication

Age

From **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

In present study, simple randomization method was used.

Blinding (investigator's opinion)

Double blinded

Blinding description

This double-blind study was carried out and the cardiologist who do echocardiography patients, as well as those taking medication or placebo, are blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences Ethics Committee

Street address

Azad Blv.- Headquarters of Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

6856568823

Approval date

2016-04-14, 1395/01/26

Ethics committee reference number

ZUMS.REC.1395.205

Health conditions studied

1

Description of health condition studied

Systolic Heart failure

ICD-10 code

I30-I52

ICD-10 code description

IX Diseases of the circulatory system

2

Description of health condition studied

Systolic Heart failure

ICD-10 code

I50.1

ICD-10 code description

Left ventricular failure

Primary outcomes

1

Description

Ejection Fraction

Timepoint

Before beginning the intervention with vitamin D and placebo and then 2 months after the intervention

Method of measurement

Echocardiography

2

Description

End Diastolic Volume

Timepoint

Before beginning the intervention with vitamin D and placebo and then 2 months after the intervention

Method of measurement

Echocardiography

3

Description

Heart Failure Class

Timepoint

Before beginning the intervention with vitamin D and placebo and then 2 months after the intervention

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Vitamin D

Timepoint

Before the intervention, then two months after the intervention with vitamin D and placebo

Method of measurement

High Performance Liquid Chromatography

2

Description

Albumin

Timepoint

Before the intervention, then two months after the intervention with vitamin D and placebo

Method of measurement

Immunoassay

3

Description

Creatinine

Timepoint

Before the intervention, then two months after the intervention with vitamin D and placebo

Method of measurement

Immunoassay

4

Description

Calcium

Timepoint

Before the intervention, then two months after the intervention with vitamin D and placebo

Method of measurement

Ion Selected (Specific) Electrode

5

Description

Phosphor

Timepoint

Before the intervention, then two months after the intervention with vitamin D and placebo

Method of measurement

Ion Selected (Specific) Electrode

Intervention groups

1

Description

Intervention group: Intervention group: A 50000 unit capsule of vitamin D, manufactured by Abidi company, is given weekly and at 50,000 units for 8 weeks. It should be noted that patients will not be aware of the type of medicine. Patients are monitored for 2 months.

Category

Treatment - Drugs

2

Description

Placebo group: Appearance of 50,000 capsules of vitamin D, manufactured by Abidi company, is given weekly for 8 weeks. It should be noted that patients will not be aware of the type of medicine. Patients are monitored for 2 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person

Dr. Reza Hassanzadeh Makuei

Street address

Ayatollah Mousavi Hospital-Gawazang Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Alireza Shoghli

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Web page address

http://zums.ac.ir/index.php?slc_lang=fa&sid=24&slct_pg_id=433

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

80

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Reza Hassanzadeh Makuei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data files related to the use of medication and medication are also the main implications of sharing.

When the data will become available and for how long

The beginning of the access period was 1 year after the publication

To whom data/document is available

Data and other study documentation will be available to all individuals and academic and non-academic institutions.

Under which criteria data/document could be used

Individuals with data receiving conditions can have the data available after receiving the documented consent of Zanjan University of Medical Sciences

From where data/document is obtainable

Visit Zanjan University of Medical Sciences at your personal or e-mail address and get consent for received information.

What processes are involved for a request to access

data/document

Individuals or institutions, in person or by email, with his introduction and explanation of the purpose of the visit to the Zanjan University of Medical Sciences has the opportunity to have information and can have information within about 1 month.

Comments