Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of the effects of vitamin D on left ventricular function and function class of patients with heart failure

Protocol summary

Summary

We enroll 60 patients with stable congestive heart failure (CHF) based on the following criteria: Inclusion Criteria: 1- ambulatory New York Heart Association (NYHA) class ≤ III, 2- LVEF ≤ 45%, 3- Stability for at least 3 months (no exacerbation, no change in medication) and exclusion Criteria: 1- Therapy with steroids or anticonvulsants and vitamin D supplements, 2- Prior history or present hypercalcemia (serum calcium≥10.5mg/dl), 3- History of renal stone, 4- Persistent atrial fibrillation (to optimize the reproducibility of our estimation of LV function). After obtaining written consent, Patients will be randomly divided in 2 groups of interventions and controls, and then will be asked to take visually identical capsules per week of either placebo or vitamin D. Intervention group will receive 50000 IU vitamin D per week for 6 months, and controls will receive exactly similar placebo (cellulose) capsules regarding shape, size and taste as cases. Treatment will be conducted for a period of 6 months. Both groups will receive a daily supplement of 500 mg oral calcium. At the base line visit and at the end of study we will perform transthoracic echocardiography to evaluate LVEF and blood sample of each subject will be taken for Ca++, p, Alb, 25(OH) D, Cr. Patients will be reviewed every month. NYHA status at the end of the study will be evaluated again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706121181N1**
Registration date: **2011-10-05, 1390/07/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-10-05, 1390/07/13

Registrant information

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Mansour Siavash
Name of organization / entity
Isfahan Endocrine and Metabolism Research Center
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2007-10-01, 1386/07/09

Expected recruitment end date

2008-09-30, 1387/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of vitamin D on left ventricular function and function class of patients with heart failure

Public title

Evaluation of the effects of vitamin D on left ventricular function and function class of patients with heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: ambulatory New York Heart Association (NYHA) Functional Class ≤ III; LV ejection fraction (LVEF) ≤ 45%.

Exclusion: hypercalcemia; nephrolithiasis; intake of supplements containing vitamin D or calcium; therapy with corticosteroids or anticonvulsants; serum creatinine concentration > 2mg/dl.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

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
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences

City
Isfahan

Postal code

Approval date
2006-03-21, 1385/01/01

Ethics committee reference number
387019

Health conditions studied

1

Description of health condition studied
Heart Failure

ICD-10 code
I50

ICD-10 code description
Heart failure

Primary outcomes

1

Description
Left ventricular ejection fraction (LVEF)

Timepoint
six months

Method of measurement
Echocardiography

2

Description
changes in Left ventricular ejection fraction

Timepoint
6 months

Method of measurement
echocardiography

Secondary outcomes

1

Description
NYHA function class

Timepoint
six months

Method of measurement
clinical interview

Intervention groups

1

Description
Intervention group will receive 50000 IU vitamin D per week for 6 months.

Category
Treatment - Drugs

2

Description
Control group will receive exactly similar placebo (cellulose) capsules regarding shape, size and taste.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Chamran Hospital

Full name of responsible person
Maryam Kerdegari

Street address

City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of medical sciences
Full name of responsible person
Peyman Adibi
Street address
Deputy of research, Isfahan University of medical sciences
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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
Isfahan University of Medical Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

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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