

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of single oral dose vitamin D on left ventricular remodelling in patients with acute anterior left ventricular infarction referred to Shahid Rajaei Hospital and comparison with randomized clinical trial control group IRCTcular

Protocol summary

Study aim

The effect of oral dose of vitamin D bolus on left ventricular remodeling in patients with acute anterior left ventricular infarction referred to Rajaei Hospital

Design

A block randomized, phase 3, double-blind mode

Settings and conduct

144 patients are divided into two groups based on a random number (block) table. The intervention group, in addition to standard treatment, receives a dose of 50,000 units of calciferol, and the control group receives only standard treatment. Upon the arrival of all patients, the vitamin d calcium and troponin checks are echoed shortly afterward and the criteria are assessed. The troponin is checked daily and the level below the troponin chart is calculated and the patient echo is repeated two months later. Then the information is entered into SPSS and the two groups are compared. It should be noted that the study is double-blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 40-85 years; diagnosis of anterior infarction less than 12 hours after the onset of symptoms; patient informed consent. Exclusion criteria: history of infarction, history of abnormal LV EF; cardiomyopathy, Vitamin D supplementation, Moderate to severe valvular disease, Calcium above 10.5, allergy to vitamin D supplementation, People with BMI >30, Life-threatening medical conditions include renal or liver failure, cancer, and rheumatic and immunological diseases.

Intervention groups

Patients with acute anterior left ventricular infarction who are referred to Rajai Hospital in Karaj will receive vitamin D if they receive <30 doses of 50,000 units of vitamin D bolus. The control group is people with deficiencies who do not receive vitamin D.

Main outcome variables

sphericity index / LV EDDI/LV ESVI/LV EDVI//LV EF / LVESDI/ LV mass/ GLS Troponin /diastolic dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211117053087N1**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-19, 1400/11/30**

Update count: **0**

Registration date

2022-02-19, 1400/11/30

Registrant information

Name

Fatemeh Basavand

Name of organization / entity

Country

Iran (Islamic Republic of)

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ffatemehhbsv@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-04, 1400/10/14

Expected recruitment end date

2022-05-04, 1401/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of single oral dose vitamin D on left ventricular remodelling in patients with acute anterior left ventricular infarction referred to Shahid Rajaei Hospital and comparison with randomized clinical trial control group IRCTcular

Public title

The effect of single oral dose vitamin D on left ventricular remodelling in patients with acute anterior left ventricular infarction referred to Shahid Rajaei Hospital and comparison with randomized clinical trial control group IRCT

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age between 40_85 patients with Anterior infarction less than 12 hours after the onset of symptoms Patient informed consent to participate in the research project

Exclusion criteria:

history of infarction history of abnormal LVEF history of cardiomyopathy History of taking vitamin D supplements Moderate to severe valvular disease Calcium above 10.5 Allergy to vitamin D supplementation Individuals with BMI above 30 m2 / kg People who are not expected to stay in the study People with any life-threatening medical conditions renal failure liver failure People with a history of any known cancer Rheumatological and immunological diseases

Age

From **40 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed by block randomization method with heterogeneous blocks 2, 4, and 6 to hide the allocation order. The randomization list will be prepared in advance using the software available on the relevant, reputable website.

(<https://www.sealedenvelope.com/simple-randomiser/v1/ists>). After the physician (responsible researcher) determines that the patient is eligible, the researcher, who has the confidential randomization list, will be

contacted to assign the patient to one of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the data analyzer and the sample collector are kept blind. These people do not know which study group the questionnaire they fill out with patients belongs to. Intervention or control. Analysts also analyze raw information in which it is not clear whether this information is for the control group or the intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz University of Medical Science

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Sara Dormitory /The entrance of Honar pool/, Nabout Boulevard, /Karaj

City

Karaj

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Postal code

3149969411

Approval date

2021-09-20, 1400/06/29

Ethics committee reference number

IR.ABZUMS.REC.1400.229

Health conditions studied**1****Description of health condition studied**

Patients with acute left ventricular anterior infarction who are candidates for angioplasty

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

LV EF

Timepoint

At the beginning of the study and two months later

Method of measurement

ECO TDI

2

Description

LVESDI

Timepoint

At the beginning of the study and two months later

Method of measurement

ECO TDI

3

Description

LVESVI

Timepoint

At the beginning of the study and two months later

Method of measurement

ECO TDI

4

Description

LVEDVI

Timepoint

At the beginning of the study and two months later

Method of measurement

ECO TDI

5

Description

LVEDDI

Timepoint

At the beginning of the study and two months later

Method of measurement

ECO TDI

6

Description

Diastolic function

Timepoint

At the beginning of the study and two months later

Method of measurement

ECO TDI

7

Description

LV MASS

Timepoint

At the beginning of the study and two months later

Method of measurement

ECO TDI

8

Description

Sphercity Index

Timepoint

At the beginning of the study and two months later

Method of measurement

ECO TDI

9

Description

GLS

Timepoint

At the beginning of the study and two months later

Method of measurement

ECO TDI

10

Description

Troponin

Timepoint

At the beginning of the study and two months later

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People in the intervention group are patients with acute anterior infarction of the left ventricle who are referred to Rajai Hospital in Karaj. If vitamin D is below 30 in the blood, they will be given a bolus dose of 50,000 units of vitamin D. And it is recommended to take one pill a week of vitamin D.

Category

Treatment - Drugs

2

Description

Control group: receives routine treatments that patients with acute anterior infarction receive and there is no change in the treatment process.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital Hesarak

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz University of Medical Sciences

Proportion provided by this source

100

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

Karaj University of Medical Sciences

Full name of responsible person

Fatemeh Basavand

Position

Consultant

Latest degree

A Level or less

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available