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 disfunction

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

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Iran (Islamic Republic of)

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+98 21 7624 1950

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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/lists). 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
Street address
Sara Dormitory /The entrance of Honar pool/, Nabout Boulevard, /Karaj
City
Karaj
Province
Alborz
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 Rajaee Hospital Hesarak
Full name of responsible person
Fatemeh Basavand
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Hamed Talakoub

Street address

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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

Cardiology

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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