Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of loading dose of vitamin D before percutaneous coronary intervention in patients with unstable angina in reducing Major adverse cardiovascular events

Protocol summary

Study aim

Evaluation of the effect of loading dose of vitamin D before percutaneous coronary intervention(PCI) in patients with unstable angina(UA) in reducing Major adverse cardiovascular events(MACE)

Design

In this Single Blind Trial, 76 patients with serum vitamin D deficiency who are candidates for percutaneous coronary intervention(PCI) are randomly divided into two parallel groups.

Settings and conduct

In patients with unstable angina(UA) who are candidates for percutaneous coronary intervention(PCI) and are admitted to Ayatollah Mousavi Hospital during 2021, a venous blood sample will be taken before PCI to measure vitamin D levels. Patients with serum vitamin D deficiency(Less than 30ng/ml) underwent telephone and in-person follow-up in the form of history, physical examination, ECG and echocardiography during 3 and 6 months after PCI, and in terms of the occurrence of Major adverse cardiovascular events(MACE) including myocardial infarction, re hospitalization, need for revascularization in re hospitalization and mortality are monitored. finally, the frequency of MACE and its components are compared between the two groups.

Participants/Inclusion and exclusion criteria

Patients over 18 years of age with unstable angina and candidates for percutaneous coronary intervention(PCI) with serum vitamin D deficiency will be deliberately admitted to the study. Patients with a history of myocardial infarction, revascularization or CABG will be excluded from the study.

Intervention groups

Patients were randomly divided into two groups before the intervention, so that the first group, in addition to routine drugs, treated with vitamin D (300,000 units orally 12 hours before PCI), and the second group will receive only routine medications.

Main outcome variables

Myocardial infarction; re hospitalization; need for revascularization in re hospitalization; mortality

General information

Reason for update

Edited by the Hospital Research Committee

Acronym

IRCT registration information

IRCT registration number: **IRCT20210228050528N1**
Registration date: **2021-10-22, 1400/07/30**
Registration timing: **prospective**

Last update: **2022-10-29, 1401/08/07**
Update count: **1**

Registration date

2021-10-22, 1400/07/30

Registrant information

Name
Amir Shahbazzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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amirshahbazzadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date
2021-10-24, 1400/08/02
Actual recruitment end date
2022-04-19, 1401/01/30
Trial completion date
2022-10-22, 1401/07/30

Scientific title
Evaluation of the effect of loading dose of vitamin D before percutaneous coronary intervention in patients with unstable angina in reducing Major adverse cardiovascular events

Public title
Evaluation of the effect of vitamin D before percutaneous coronary intervention in the prevention of cardiovascular complications
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with unstable angina who are candidates for PCI Patients with deficient serum levels of vitamin D
Exclusion criteria:
Previous history of myocardial infarction Previous history of revascularization therapy interventions Patients with a previous history of CABG Patients with failed PCI Simultaneous involvement of valvular disorders Take vitamin D, calcium or omega-3 supplements in the last 3 months Patients with hypercalcemia, nephrolithiasis, sarcoidosis, malabsorption syndromes Chronic underlying diseases such as liver, kidney or rheumatic disorders Pregnancy and lactation Having malignancies History of receiving corticosteroids or immunosuppressants in the last 6 months
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **76**
Actual sample size reached: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients are divided into simple randomizations using randomly generated computer-generated numbers by an independent individual.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, patients will be unaware of the nature of the prescribed drug, that is, after randomly dividing patients into two groups, the first group in addition to routine pre-intervention drugs, treated with vitamin D (three hundred thousand units orally 12 Hours before the intervention), and the second group will receive only routine pre-intervention medications.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences
Street address
Ayatollah Mousavi Hospital, Gavazang Boulevard
City
Zanjan
Province
Zanjan
Postal code
4513956183
Approval date
2021-09-01, 1400/06/10
Ethics committee reference number
IR.ZUMS.REC.1400.218

Health conditions studied

1

Description of health condition studied
Major adverse cardiovascular events
ICD-10 code
R94.30
ICD-10 code description
Abnormal result of cardiovascular function study, unspecified

2

Description of health condition studied
Precutaneous coronary intervention
ICD-10 code
Z95.5
ICD-10 code description
Presence of coronary angioplasty implant and graft

3

Description of health condition studied
Unstable angina
ICD-10 code
I25.110
ICD-10 code description
Atherosclerotic heart disease of native coronary artery with unstable angina pectoris

Primary outcomes

1

Description
Number of myocardial infarction cases
Timepoint
3 and 6 months later
Method of measurement
ECG and echocardiography

2

Description
Number of revascularization cases in re hospitalization
Timepoint
3 and 6 months later
Method of measurement
ECG and echocardiography

Secondary outcomes

1

Description
Readmission rate
Timepoint
3 and 6 months later
Method of measurement
ECG and echocardiography

2

Description
Mortality rate
Timepoint
3 and 6 months later
Method of measurement
In-person and telephone follow-up

3

Description
Cardiac function
Timepoint
3 and 6 months later
Method of measurement
In-person follow-up

Intervention groups

1

Description
Intervention group: A group that, in addition to routine pre-PCI medications, is treated with 300,000 units of oral vitamin D (six 50,000 units of vitamin D tablets produced by Zahravi Pharmaceutical Company) 12 hours before PCI.
Category
Treatment - Drugs

2

Description
Control group: The group that only receives routine medications before PCI.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital
Full name of responsible person
Amir shahbazzadeh
Street address
Gavazang Boulevard
City
Zanjan
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4513956183
Phone
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Mousavihospital@zums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Alireza shoghli
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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Amir Shahbazzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
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No 232, block C, Honarmandan tower, Shariati Blvd, Zanjan
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Person responsible for updating data

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amirshahbazzadeh@yahoo.com

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
Part of the data, such as information about the primary or secondary outcome, will be shared.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers in academic and scientific institutions
Under which criteria data/document could be used
The data and documents of the study will be available for the use of other researchers in academic and scientific institutions in relation to related topics with ethical principles.
From where data/document is obtainable

My e-mail address : Amirshahbazzadeh@yahoo.com

What processes are involved for a request to access data/document

The applicant can access the study data and documents after submitting the requirement on reputable sites and online correspondence with me.

Comments