Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

the comparison of Effect of calcitriol and cholecalciferol on cardiac biomarkers in patients undergoing elective percutaneous coronary intervention, a randomized controlled study

Protocol summary

Study aim

Evaluation of the effect of cholecalciferol or calcitriol addition to the pre operation standard regimen in the decrease of cardiac injury following elective percutaneous coronary intervention

Design

Phase 3 randomized, blinded, parallel design clinical trial on 180 patients. Randomization will be performed by rand function in Excell software.

Settings and conduct

This clinical trial will be conducted in Alzahra and Shahid Faghihi medical centers affiliated to shiraz university of medical sciences on patients receiving elective percutaneous coronary intervention. patients will assign to receive cholecalciferol or calcitriol orally prior to the intervention.

Participants/Inclusion and exclusion criteria

patients with the diagnosis of ischemic heart disease with the age of 18 to 80 with vitamin D level of less than 30 ng/mL years who are candidate to receive percutaneous coronary intervention will be recruited. patients with the elevated cardiac biomarker or history of myocardial infarction or who received coronary artery bypass graft in the last 3 months, history of receiving cholecalciferol or calcitriol or a containing multi vitamin in the last month or received unsuccessful percutaneous coronary intervention will be excluded from the study,

Intervention groups

Included patients will assign in intervention group 1, intervention group 2 or control group. patients in intervention group 1 will receive cholecalciferol by the dose of 300000, in intervention group 2 will receive calcitriol by the dose of 1 micro gram in intervention group. Patients in control group will receive no intervention.

Main outcome variables

Elevation of Troponin I and High sensitivity C-reactive protein and Creatine kinase-MB

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150518022306N3**
Registration date: **2020-08-20, 1399/05/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-20, 1399/05/30**
Update count: **0**

Registration date

2020-08-20, 1399/05/30

Registrant information

Name
Sara Asadi
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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+98 71 3242 4128
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the comparison of Effect of calcitriol and cholecalciferol on cardiac biomarkers in patients undergoing elective percutaneous coronary intervention, a randomized controlled study

Public title

Calcitriol and cholecalciferol effect on cardiac biomarkers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients diagnosed with Coronary artery disease who hospitalized due to performing elective percutaneous Coronary Intervention (angioplasty with stent) Vitamin D level of less than 30 ng/mL

Exclusion criteria:

patients with myocardial infarction or history of coronary artery bypass graft in last 3 months patients with history of vitamin D supplementation in the last 1 month prior to hospitalization patients with history of unsuccessful PCI

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will assign to two intervention groups and a control group via computer generated simple randomization method. The random allocation sequence will computer generate and consist of series of group number (either 1 = A or 2 = B) for each consecutive patient. Computer generated randomization will be performed by Excel software via #Rand function.

Blinding (investigator's opinion)

Single blinded

Blinding description

All patients were assigned to two intervention groups or a control group, randomly by principle investigator. Data analyzer will be blinded to the randomization and group assignment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Fars Province, Shiraz, Zand st,

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸۱۴۳۳۶

Approval date

2019-05-08, 1398/02/18

Ethics committee reference number

IR.SUMS.REC.1398.513

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

comparison any change in level of troponin-I

Timepoint

at baseline and 24 hours after Percutaneous Coronary Intervention

Method of measurement

serum level

2

Description

comparison any change in level of High Sensitivity C-Reactive Protein (hsCRP)

Timepoint

At baseline and 24 hours after Percutaneous Coronary Intervention

Method of measurement

serum level

3

Description

comparison any change in level of Creatine kinase-MB

Timepoint

At baseline and 24 hours after Percutaneous Coronary Intervention

Method of measurement
serum level

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: recieving 300000 internatinal unit cholecalciferol orally 12 hours before Percutaneous Coronary Intervention (Daana Pharma)
Category
Prevention

2

Description
Intervention group: recieving 1 microgram orally 6 hours before Percutaneous Coronary Intervention (Zahravi Pharmaceutical Company)
Category
Prevention

3

Description
Control group: will receive no intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra cardiac medical center
Full name of responsible person
Dr. Laleh Mahmoudi
Street address
Alzahra charity hospital, blvd siboieh, Shiraz
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2

Recruitment center
Name of recruitment center
Shahid Faghihi medical and educational center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Laleh Mahmoudi
Position

Associated professor
Latest degree
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Person responsible for updating data

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Web page address

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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Primary and secondary outcome data after making unrecognizable will be released
When the data will become available and for how long
6 months after publishing the results of primary outcome
To whom data/document is available
Any researchers will have access to the data after allowance of corresponding author
Under which criteria data/document could be used
Performing any analysis to any data resulted form this study will be allowed only with the permission of corresponding author
From where data/document is obtainable
Correspondance
What processes are involved for a request to access data/document
After requesting for data, correspondence will check the authorization and then they will be informed about it
Comments