

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 71 3242 4128

Email address

asadi_s@sums.ac.ir

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: receiving 300000 international unit
cholecalciferol orally 12 hours before Percutaneous
Coronary Intervention (Daana Pharma)

Category

Prevention

2**Description**

Intervention group: receiving 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

City

Shiraz

Province

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7164904937

Phone

+98 71 3739 8811

Email

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2**Recruitment center****Name of recruitment center**

Shahid Faghihi medical and educational center

Full name of responsible person

Dr. Laleh Mahmoudi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ali Dehshahri

Street address

Fars Province, Shiraz, Rokn Abad Town, Marvdasht
Hwy, Karafarin st

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7146844680

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dehshahria@sums.ac.ir

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

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Fars province, Shiraz, Marvdasht highway, Karafarin st.

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Latest degree

Medical doctor

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Laleh Mahmoudi

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sara Asadi

Position

Clinical resident

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 from 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