Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of the Effects of Calcitriol on Ischemia-reperfusion Injury and Inflammatory Biomarkers in Patients Undergoing Percutaneous Coronary Intervention (PCI)

Protocol summary

Study aim

Determination of the effects of Calcitriol on inflammation and ischemia-reperfusion injury following PCI

Design

This is a randomized parallel, single-blinded, trial which was performed on 72 patients who were candidated for percutaneous coronary intervention (PCI) interventions and were eligible for inclusion in the study. After obtaining written consent, the patients were randomly assigned to two groups of the intervention and the control group.

Settings and conduct

This study was conducted in Shahid Modarres Hospital of Shahid Beheshti University of Medical Sciences. After obtaining written consent, the patients were randomly assigned into two groups of calcitriol and the control group. To evaluate the efficacy of calcitriol, sampling was performed from all patients at baseline and 24 hours after performing PCI. In order to do blindness, the main investigator, those who evaluate the outcome, and the data analyst did not know the allocation of the groups until the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all individuals over the age of 18 years old who referred to Shahid Modarres Educational Hospital of Shahid Beheshti University of Medical Sciences for elective PCI; Exclusion criteria: serum creatinine level greater than 2 mg/dL, active metabolic bone disease, severe liver disease, receiving anti-inflammatory drugs (except aspirin and statin), vitamin D supplementation consumption, patients with ejection fraction less than 30%

Intervention groups

In the intervention group, in addition to the center protocol, the patients were administered 3 µg injectable calcitriol before PCI. In the control group, no additional drugs to the protocol were prescribed.

Main outcome variables

Evaluation of the relationship between injectable calcitriol administration and the level of inflammatory biomarkers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N10**
Registration date: **2018-11-30, 1397/09/09**
Registration timing: **retrospective**

Last update: **2018-11-30, 1397/09/09**
Update count: **0**

Registration date

2018-11-30, 1397/09/09

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

f_dastan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date
2017-10-23, 1396/08/01
Actual recruitment end date
2018-06-20, 1397/03/30
Trial completion date
2018-09-22, 1397/06/31

Scientific title
Evaluation of the Effects of Calcitriol on Ischemia-reperfusion Injury and Inflammatory Biomarkers in Patients Undergoing Percutaneous Coronary Intervention (PCI)

Public title
Evaluation of the Effect of Calcitriol on the Percutaneous Coronary Intervention
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients referring to Shahid Modarres hospital cath lab Patients more than 18 years old Patients who are candidated for elective PCI surgery
Exclusion criteria:
Serum creatinine level more than 2 mg/dL Active metabolic bone disease Vitamin D supplementation receivement Consuming anti-inflammatory drugs (except aspirin and statin) Severe hepatic disease (Child-paugh C) Ejection fraction less than 30% Contraindications or hypersensitivity to calcitriol
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
More than 1 sample in each individual
Number of samples in each individual: **2**
One blood clot sample was taken before surgery and one sample was taken 24 hours after PCI.
Actual sample size reached: **72**
More than 1 sample in each individual
Actual sample size in each individual: **2**
One blood clot sample was taken before surgery and one sample was taken 24 hours after PCI.
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, tools used in randomization: table of random numbers
Blinding (investigator's opinion)
Single blinded
Blinding description
Investigator, outcome assessors, and data analyser were blind to the study groups untill the end of the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of School of Pharmacy, Nursing, and Midwifery; Shahid Beheshti University of Medica
Street address
No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran
City
Tehran
Province
Tehran
Postal code
1991953381
Approval date
2017-10-09, 1396/07/17
Ethics committee reference number
IR.SBMU.PHNM.1396.824

Health conditions studied

1

Description of health condition studied
Percutaneous coronary intervention (PCI)
ICD-10 code
I25.110
ICD-10 code description
Atherosclerotic heart disease of native coronary artery with unstable angina pectoris

Primary outcomes

1

Description
Change in CK-MB serum level
Timepoint
Before surgery and 24 hours after percutaneous coronary intervention
Method of measurement
Laboratory kit measuring serum level of CK-MB

2

Description
Change in Interleukin-6 serum level
Timepoint
Before surgery and 24 hours after percutaneous coronary intervention

Method of measurement
Laboratory kit measuring serum level of interleukin 6

3

Description
Change in total high sensitivity CRP serum level
Timepoint
Before surgery and 24 hours after percutaneous coronary intervention
Method of measurement
Laboratory kit measuring serum level of high sensitivity CRP

4

Description
Change in cardiac Troponin I serum level
Timepoint
Before surgery and 24 hours after percutaneous coronary intervention
Method of measurement
Laboratory kit measuring serum level of cardiac Troponin I

Secondary outcomes

1

Description
myocardial infarction (MI)
Timepoint
90 to 100 days after intervention
Method of measurement
Check patient records and verbal interview at clinic

2

Description
The need for Percutaneous Coronary Intervention (PCI)
Timepoint
90 to 100 days after intervention
Method of measurement
Check patient records and verbal interview at clinic

3

Description
The need for Coronary Artery Bypass Graft (CABG)
Timepoint
90 to 100 days after intervention
Method of measurement
Check patient records and verbal interview at clinic

4

Description
All-cause death
Timepoint
90 to 100 days after intervention
Method of measurement
Check patient records and telephone interview

Intervention groups

1

Description
Intervention group: Administration of 3 µg of injectable calcitriol intravenous, 3 hours before performing PCI
Category
Prevention

2

Description
Control group: No intervention was made.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modarres Hospital
Full name of responsible person
Mohammad Mahdi Hashempour
Street address
Yadegar-e-Imam Highway and Saadat Abad junction, Sadat Abad Street
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2207 4087
Email
hashempourmm@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahereh Shams
Street address
No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
pr_pharmacy@sbmu.ac.ir
Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammad Mahdi Hashempour

Position
board certified clinical pharmacist

Latest degree
Specialist

Other areas of specialty/work
Clinical pharmacy

Street address
No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran

City
Tehran

Province
Tehran

Postal code
1991953381

Phone
+98 21 8820 0118

Email
hashempourmm@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Farzaneh Dastan

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
clinical pharmacy

Street address
No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran

City
Tehran

Province
Tehran

Postal code
1991953381

Phone
+98 21 8820 0118

Email
f_dastan@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Farzaneh Dastan

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
clinical pharmacy

Street address
No. 2660, Vali-e Asr St., Niyayesh junction, Tehran

City
Tehran

Province
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1991953381

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f_dastan@sbmu.ac.ir

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
Not applicable