Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Study of effect of calcitriol in preventing contrast induced nephropathy among patients with kidney dysfunction undergoing coronary angiography or interventions

Protocol summary

Study aim
Effect of calcitriol in preventing contrast induced nephropathy among patients with renal dysfunction undergoing coronary angiography or intervention

Design
A double blind randomized control trial, with a parallel group design of 236 patients, enrolled between September 2016 through July 2017, and followed for one year

Settings and conduct
sampling was done in educational hospitals of Shahid Beheshti University of Medial Science. patients and doctors were blind about drug and placebo coding

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adults above 18 years old referring to Taleghani hospital for PCI with Scr ≥ 1.3 mg/dl or GFR ≤ 60ml/min Exclusion criteria: Active metabolic bone dis, Allergy to vitamin D, vitamin supplementation through 7 days ago, dialysis ,severe hepatic dis.

Intervention groups
patients over 18 years old that were admitted in educational hospitals of shahid beheshti university of medical science in two groups of placebo and calcitriol

Main outcome variables
cystatin C and glumerolar filtration Rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160412027346N7**
Registration date: **2019-05-13, 1398/02/23**
Registration timing: **retrospective**

Last update: **2019-05-13, 1398/02/23**
Update count: **0**

Registration date
2019-05-13, 1398/02/23

Registrant information

Name
Shadi Ziaie
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-06-21, 1395/04/01

Expected recruitment end date
2017-09-22, 1396/06/31

Actual recruitment start date
2016-06-21, 1395/04/01

Actual recruitment end date
2017-09-06, 1396/06/15

Trial completion date
2017-09-06, 1396/06/15

Scientific title
Study of effect of calcitriol in preventing contrast induced nephropathy among patients with kidney dysfunction undergoing coronary angiography or interventions

Public title
calcirtiol effect in contrast induced nephropathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults above 18 years old referring to Taleghani hospital for PCI with Scr ≥ 1.3 mg/dl or GFR ≤ 60ml/min
Exclusion criteria:
Active metabolic bone dis, Allergy to vitamin D, vitamin supplementation through 7 days ago, dialysis ,severe hepatic disease.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **236**
More than 1 sample in each individual
Number of samples in each individual: **2**
Two blood samples in 24 hours interval were taken from patients
Actual sample size reached: **236**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Two blood samples in 24 hours interval were taken from patients

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization by excel software

Blinding (investigator's opinion)
Double blinded

Blinding description
Drug an placebo were similar in shape and packaging. code A belongs to placebo and code B belongs to drug. Only main researcher known the code. cardiologists that were blind about coding system, gave drug or placebo to patients

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Yaman Ave
City
Tehran
Province
Tehran
Postal code
1985717443

Approval date
2016-04-03, 1395/01/15

Ethics committee reference number
IR.SMMU.PHNM.1395.503

Health conditions studied

1

Description of health condition studied
effect of calcitriol in preventing contrast induced nephropathy in patients with renal function undergoing coronary angiography or intervention.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
serum level of cystatin C and its changes

Timepoint
at the beginning of angiography and 24 hours later

Method of measurement
using lab kit with considering elisa method, serum concentration of cystatin c was measured.

Secondary outcomes

1

Description
serum level of creatinine

Timepoint
at baseline and 24 h after intervention

Method of measurement
using lab kit with turbidimetry method.

Intervention groups

1

Description
Intervention group: Adults above 18 years old referring to educational hospital for PCI with Scr ≥ 1.3 mg/dl or GFR ≤ 60ml/min were enrolled in study . patients receive 3 calcitriol tabs 3 and 12 hours before procedure .

Category
Treatment - Drugs

2

Description
Control group: in control group , Adults above 18 years old referring to educational hospital for PCI with Scr ≥ 1.3 mg/dl or GFR ≤ 60ml/min were enrolled in study patients receive 3 placebo tabs 3 and 12 hours before procedure
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
educational hospitals of shahid beheshti university of medical science
Full name of responsible person
solmaz hassani
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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
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
50
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
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shadi ziaie
Position
resident of clinical pharmacy
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Medical doctor
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Person responsible for updating data

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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
All data can be accessible in excel form
When the data will become available and for how long
After publishing the article
To whom data/document is available
Academic members can have access to data.
Under which criteria data/document could be used
for doing similar research, data can be used.
From where data/document is obtainable
they can refer to first author
What processes are involved for a request to access data/document
one week after sending email, data file will be sent
Comments
None