

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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 Medical 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  $\geq$  1.3 mg/dl or GFR  $\leq$  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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8887 3704

###### Email address

shadiziaie@sbmu.ac.ir

##### 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  $\geq$  1.3 mg/dl or GFR  $\leq$  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  $\geq$  1.3 mg/dl or GFR  $\leq$  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  $\geq$  1.3 mg/dl or GFR  $\leq$  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

##### Street address

Yaman Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 8887 3704

##### Email

s\_hassani\_85@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

shadi ziaie

##### Street address

Yaman Ave

##### City

tehran

##### Province

Tehran

##### Postal code

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##### Phone

+98 21 8887 3704

##### Email

s\_hassani\_85@yahoo.com

##### 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

##### Full name of responsible person

shadi ziaie

##### Position

resident of clinical pharmacy

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Yaman Ave

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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

shadi ziaie

##### Position

assisstant 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Shadi Ziaie

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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**Province**

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**Fax****Email**

shadiziaie@sbm.ac.ir

**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