

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effect of preoperative calcitriol on inflammatory markers following percutaneous nephrolithotomy (PCNL): a randomized controlled trial

#### Protocol summary

##### Study aim

Determining the effect of preoperative calcitriol on inflammatory factors after percutaneous nephrolithotomy

##### Design

A randomized, single-blinded, controlled clinical trial with a parallel groups design of 14 patients using block randomization

##### Settings and conduct

This study will be conducted in Faghihi hospital, Shiraz. Patients will be divided into two groups (intervention and control). Patients in the intervention groups will receive 2 mcg of intravenous calcitriol two hours before the operation, while patients in the control groups will receive normal saline. Serum inflammatory markers will be recorded both before and 24 hours after the operation. Participants are blinded to the study, but the surgeon knows the contents of the ampules.

##### Participants/Inclusion and exclusion criteria

Patients above 18 years of age who undergo percutaneous nephrolithotomy will be included. However, patients with use of vitamin D supplements, serum vitamin D of above 100 nmol/L, high serum calcium, use of NSAIDs, previous history of allergic reactions to calcitriol, and metabolic bone diseases will be excluded.

##### Intervention groups

Intervention group: 2 mcg intravenous calcitriol two hours before the operation  
Control group: intravenous normal saline two hours before the operation

##### Main outcome variables

Serum inflammatory factors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230815059154N1**

Registration date: **2023-08-26, 1402/06/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-26, 1402/06/04**

Update count: **0**

##### Registration date

2023-08-26, 1402/06/04

##### Registrant information

###### Name

Abdolreza Haghpanah

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3235 1087

###### Email address

rezahaghpanah@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2023-12-06, 1402/09/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of preoperative calcitriol on inflammatory markers following percutaneous nephrolithotomy (PCNL): a randomized controlled trial

##### Public title

Effect of calcitriol on post-percutaneous nephrolithotomy

inflammation

### **Purpose**

Supportive

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Patients above 18 years of age Patients undergoing percutaneous nephrolithotomy

#### **Exclusion criteria:**

Using vitamin D supplements Serum vitamin D level above 100 nmol/L High serum calcium level Using of NSAID drugs Previous allergic reactions to calcitriol Having metabolic bone diseases Not willing to participate in the study

### **Age**

From **18 years** old

### **Gender**

Both

### **Phase**

3

### **Groups that have been masked**

- Participant

### **Sample size**

Target sample size: **14**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Patients will be divided into placebo groups and the study group in a 1 to 1 ratio and block randomization. This randomization is done by the following website: <https://www.sealedenvelope.com/simple-randomiser/v1/lists> In this type of randomization, which helps to equalize the number of samples in two groups, patients are divided into blocks (for example, 4, 6, or 8 people) in which an equal number of patients from each group are placed in each block. Then, blocks are selected randomly by the above site and randomization is done. Using the site, a list of the order of patients belonging to each group is prepared. The drug package related to the placebo and the drug is the same, it has no name and the patient cannot distinguish whether it is a placebo or a drug, but the surgeon knows the content of the ampoule and according to the random list prepared, the drug or placebo will be injected to the patient after re-explanation.

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

Participants are blinded to the study. The drug package related to placebo and drug is the same, it does not have a name, and the patient cannot distinguish whether it is a placebo or a drug, but the surgeon knows the contents of the ampule.

### **Placebo**

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**

Central building of Shiraz University of Medical Sciences, in front of Palestine street, Zand Ave.

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

7134814336

#### **Approval date**

2023-07-15, 1402/04/24

#### **Ethics committee reference number**

IR.SUMS.MED.REC.1402.190

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Kidney stone

#### **ICD-10 code**

N20

#### **ICD-10 code description**

Calculus of kidney and ureter

## **Primary outcomes**

### 1

#### **Description**

Serum inflammatory factors

#### **Timepoint**

Before operation and 24 hours after operation

#### **Method of measurement**

Laboratory kits

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: 2 mcg intravenous calcitriol injection two hours before the operation

#### **Category**

Treatment - Drugs

## 2

### Description

Control group: intravenous normal saline injection two hours before the operation

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faghihi hospital

##### Full name of responsible person

Abdolreza Haghpanah

##### Street address

Shahid Faghihi hospital, Zand Ave.

##### City

Shiraz

##### Province

Fars

##### Postal code

7134846114

##### Phone

+98 71 3235 1087

##### Email

rezahaghpanah@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mohammad Hashem Hashempur

##### Street address

Central building of Shiraz University of Medical Sciences, in front of Palestine street, Zand Ave.

##### City

Shiraz

##### Province

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##### Postal code

7134814336

##### Phone

+98 71 3230 5410

##### Email

hashempurm@sums.ac.ir

##### Grant name

##### Grant code / Reference number

IR.SUMS.MED.REC.1402.190

##### 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

10

### 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

Abdolreza Haghpanah

##### Position

Assistant professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Urology

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Shahid Faghihi hospital, Zand Ave.

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

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Abdolreza Haghpanah

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Abdolreza Haghpanah

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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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

As long as we want to share the result of our study, we will write a paper that contains all the information about our study, such as method, analysis, and results. Also, if the journal or other researchers ask us to share our patients' data and their informed consent, we will be ready to share them.

**When the data will become available and for how long**

After the paper is published

**To whom data/document is available**

All the researchers that prove they are researchers

**Under which criteria data/document could be used**

Researchers can use the data only for their personal use. The data cannot be used for their papers because it causes data duplication.

**From where data/document is obtainable**

By sending an email to the corresponding author who is Dr. Haghpanah. His email address: rezahaghpanah@yahoo.com

**What processes are involved for a request to access data/document**

Researcher who needs our data must introduce his/her completely (including his/her name and family name, occupation, place of work, address) and introduce us two to three of his/her previous studies along with the request email. After the researchers' information is confirmed by the responsible author, the documents will be sent to them as soon as possible after receiving the email. Before sending, the documents or files are checked for the personal information of the patients, and if any part of the information is personal, such as their name and national code, that information is deleted from the documents so that the identity of the patients is not revealed.

**Comments**