Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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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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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
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