

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of relationship between vitamin D supplementation treatment and hypercalciuria in patients with kidney stones

Protocol summary

Study aim

Determination of calcium levels in the urinary tract of patients with renal stone before and after vitamin D supplementation

Design

Study Type: Clinical Trial with Control Group
Sample: Patients with urinary stone age 18-65 years old diagnosis of stone and serum vitamin D have less than 30 ng / ml
Sample size: 90 people were selected

Settings and conduct

Blood samples are taken from patients referring to the nephrology clinic and serum levels of calcium, phosphorus PTH, vitamin D (25 (OH) VitD) are measured, as well as 24-hour urine sample volume, creatinine, calcium, and urine samples. Patients were randomly divided into two groups of 45 each. For 45 patients, oral vitamin D administration will start at 50,000 units for another 45 patients with oral placebo starting 1 month after the end of vitamin D and placebo administration. Sampling is performed again from both study groups and the above cases are reviewed again

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients with kidney stones and vitamin D deficiency - People aged 18-65 years - Acceptance to participate in the project - Signing a written consent - No vitamin D supplementation before study - Not having malabsorption syndromes
Conditions of Use: - Drug use including drugs such as diuretics, potassium citrate - Pregnant women - Recent stone disposal - Ureteral stone leads to blockage Urinary tract infection for the last two weeks - Systemic infection in the last two weeks - Following the intervention

Intervention groups

Intervention group 1: Patients with vitamin D level (25 (OH) VitD lower than 30 (ng / ml)) will receive 50,000 units of oral vitamin D daily for 8 weeks. Intervention group 2: Patients with vitamin D level (25 (OH) VitD less than 30 (ng / ml)) are given weekly placebo for up to 8 weeks.

Main outcome variables

Urine calcium level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046012N1**

Registration date: **2021-01-03, 1399/10/14**

Registration timing: **retrospective**

Last update: **2021-01-03, 1399/10/14**

Update count: **0**

Registration date

2021-01-03, 1399/10/14

Registrant information

Name

Elham Javadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5586

Email address

elham.javadian1396@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of relationship between vitamin D supplementation treatment and hypercalciuria in patients with kidney stones

Public title

Evaluation of relationship between vitamin D supplementation treatment and hypercalciuria in patients with kidney stones

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

- Patients with kidney stones and vitamin D deficiency referred to Zahedan Nephrology Clinic - People aged 18-65 years Acceptance to participate in the project Lack of specific illnesses such as heart failure, kidney or liver disease Absence of inflammatory or infectious diseases Not taking medications like diuretics Not taking corticosteroids Not taking immunosuppressive drugs Not taking vitamin D supplement before study

Exclusion criteria:

- Medication including drugs such as diuretics, potassium citrate - Pregnant women - Recent stone disposal Ureteral stone leads to obstruction Urinary tract infection for the last two weeks - Systemic infection in the last two weeks

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients will be done by the responsible researcher using a table of random numbers Randomization will be recorded on an Excel file by the principal investigator. Participants will be randomized via permuted block randomization. Each block will be consistent of sizes of 4 patients. For assignment of each patient to the drug or placebo group, for each patients a unique code consistent of 2 letters and a digit will be assigned. the code will be unique for each patient (for example code AB1 for first patient). Only the principle investigator will be informed of the assignment of each code to the medication or placebo group

Blinding (investigator's opinion)

Double blinded

Blinding description

1- The nurse who gives the medication to the patients whether or not they are on the medication is not aware Patients were or were not aware of the drug 3. The laboratory does not know which sample belongs to the control group

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of zahedan University of Medical Sciences

Street address

Sistan and Baluchestan Zahedan - Persian Gulf Highway - Imam Khomeini Mosque - Ali Bin Abi Talib Hospital

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Approval date

2020-01-04, 1398/10/14

Ethics committee reference number

IR.ZAUMS.REC.1398.347

Health conditions studied**1****Description of health condition studied**

Hypercalciuria in patients with kidney stones

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Increased urinary calcium level

Timepoint

24-hour urine calcium measurement at baseline (before intervention) and 3 months after intervention

Method of measurement

Laboratory measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People with kidney stones who have vitamin D levels below 30 ng / ml are prescribed oral vitamin D 50,000 units weekly for up For each patient, training sessions are held before and after the intervention, and in this study, the product of Zahravi Company is used.to 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: People with kidney stones who have vitamin D levels below 30 ng / ml are given weekly placebo for up to 8 weeks.For each patient, training sessions are held before and after the intervention, and in this study, the product of Zahravi Company is used.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ebn Abitaleb Hospital

Full name of responsible person

Ali Alidadi

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Ali ebn AbiTaleb Hospital ., Persian Gulf Highway

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<https://Alihos.zaums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Nourmohammad Bakhshani - Deputy of Research and Technology of the University

Street address

Ali Bin Abi Talib Hospital ., Persian Gulf Highway ., Zahedan town ., sistan and Baluchestan province

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Postal code

9816743111

Phone

+98 54 3329 5570

Email

Alihos@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

elham javadian

Position

Internal medicine assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

elham javadian

Position

Internal medicine assistant

Latest degree

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Other areas of specialty/work

Internal Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

The whole potential data is unpublished after being unidentifiable

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only available to scholars working in academic and academic institutions

Under which criteria data/document could be used

Use of study data is permitted for any use by researchers working in academic and scientific institutions

From where data/document is obtainable

Ali ebn Abitalib Hospital, Zahedan, Department of intral Deputy of Research of Zahedan University of Medical Sciences, Faculty of Medicine Dr. Ali Alidadi, professor of the thesis, telephone number 09120621590

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

It takes about 1 month from the request of the applicant to access data files or time documentation

Comments