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
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Iran (Islamic Republic of)
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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
Street address
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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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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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