Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Oral Cholecalciferoleffests on proteinuria and urinary TGF-β1and urinary MCP-1in non-diabetic nephropathy patients on established renin–angiotensin–aldosterone system inhibition

Protocol summary

Study aim
Determining the effect of oral vitamin D on urinary protein, TGF-β1, and urinary MCP-1 levels in non-diabetic renal patients

Design
A quasi-clinical trial, without a control group, without randomization, and without blinding, will be conducted in a clinical phase 2-3 on 40 patients.

Settings and conduct
This study will be conducted on chronic kidney disease patients referred to the urology department of Shariati Hospital, Isfahan. Before the intervention, urinary levels of protein, TGF-β1, and MCP-1 will be measured. Then, patients will be given oral vitamin D at a dose of 50,000 IU (one capsule weekly) for 4 months. At the following 2-month and 4-month time points, urinary levels of protein, TGF-β1, and MCP-1 will be measured and compared with baseline values.

Participants/Inclusion and exclusion criteria
Participants in the study will be non-diabetic kidney patients. Age over 18 years, body mass index less than 30, and no diabetes were included in the study, and vitamin D levels less than 20 ng/mL, a history of immunosuppressive drugs, and hypercalcemia, kidney stones, and arteriosclerosis were excluded from the study.

Intervention groups
The intervention group will receive 50,000 IU (one capsule weekly) of Cholecalciferol (oral vitamin D) for 4 months.

Main outcome variables
The main outcome included changes in urinary protein, TGF-β1, and MCP-1.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151123025202N43**
Registration date: **2024-11-28, 1403/09/08**
Registration timing: **prospective**

Last update: **2024-11-28, 1403/09/08**
Update count: **0**

Registration date
2024-11-28, 1403/09/08

Registrant information

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Name of organization / entity
Hamedan University of Medical Of Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-05, 1403/09/15

Expected recruitment end date
2025-07-06, 1404/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Oral Cholecalciferoleffests on proteinuria and urinary TGF-β1and urinary MCP-1in non-diabetic nephropathy patients on established renin–angiotensin–aldosterone system inhibition

Public title
ˌhe effect of vitamin D on kidney function in non-diabetic nephropathy patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having proteinuria, persistent (at least 3 months) excretion daily proteinuria more than 150 mg Age >18 years BMI≥30 kg/m2
Exclusion criteria:
Having diabetes Vitamin D level less than 20 ng/ml Receiving immunosuppressive drugs within the past 3 months Hypercalcemia, kidney stones, and arteriosclerosis
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of IsfahanUniversity of Medical Sciences
Street address
Hezar Jrip
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-12-27, 1402/10/06
Ethics committee reference number
IR.MUI.MED.REC.1402.360

Health conditions studied

1

Description of health condition studied
Chronic kidney disease
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Changes in urine protein
Timepoint
Before starting treatment, at the end of the second month, and at the end of the fourth month after starting treatment
Method of measurement
24-hour urine protein test

2

Description
Urinary TGF-β1 changes
Timepoint
Before starting treatment, at the end of the second month, and at the end of the fourth month after starting treatment
Method of measurement
Urine test

3

Description
Urinary MCP-1 changes
Timepoint
Before starting treatment, at the end of the second month, and at the end of the fourth month after starting treatment
Method of measurement
Urine test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They will receive 50,000 IU (one capsule per week) of Cholecalciferol (oral vitamin D) for 4

months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khorshid Medical Edicational Complex

Full name of responsible person
Dr. Mojgan Mokhtari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Hamedan University of Medical Sciences

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Abbas Moradi

Position
Coach

Latest degree
Master

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Epidemiology

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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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data can be shared except for authors names
When the data will become available and for how long
From 2026 onwards it is permissible
To whom data/document is available
Clinical professionals and Researchers in all fields
Under which criteria data/document could be used
For treatment of patients and develop research and science
From where data/document is obtainable
Correspond to the email address of the scientific responsible for the study
What processes are involved for a request to access data/document
Send and receive email
Comments