

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of vitamin D effect on reduction of proteinuria in patients with diabetic nephropathy and vitamin d deficiency

Protocol summary

Summary

Objective: This is a randomized, double-blinded, placebo-controlled phase 2 trial to prospectively test the effectiveness of oral vitamin d in reduction of proteinuria in patients with diabetic nephropathy and vitamin D deficiency. Inclusion criteria: having type 2 diabetes; diabetic nephropathy; vitamin D deficiency; GFR> 60 and receiving stable doses of ACE inhibitors or ARBs for 3 months or more. Exclusion criteria: glomerulonephritis; serum phosphorus level greater than 5.2 mg/dL; serum calcium level (adjusted for albumin) greater than 10.0 mg/dL; active malignancy; likelihood of requiring renal replacement therapy within 1 year or uncontrolled hypertension. Design and intervention: at enrollment, 50 patients with diabetic nephropathy and vitamin D deficiency, will be randomly assigned into 1 of 2 parallel groups: group A: 30 persons will enroll in the case group and treatment will be initiated with oral vitamin D(pearl 50000IU) one pearl every week for 12 week or group B: 30 patients will be received placebo, 1 pearl/ weekly for 12 week. After 12 weeks the patients, will be checked for 25-hydroxy vitamin D levels and the patient in placebo group will receive vitamin D. Patients were examined at baseline, 12 weeks and at the end of the study. Main outcomes: in every session UACR(urine albumin creatinin ratio) at first morning void will be assessed. The efficacy measure was the percentage change mean UACR from baseline to the last measurement during treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204049374N1**

Registration date: **2012-08-07, 1391/05/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-07, 1391/05/17

Registrant information

Name

Nooshin Ahmadi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences and Isfahan Endocrine and Metabolism Research Center

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of vitamin D effect on reduction of proteinuria in patients with diabetic nephropathy and vitamin d deficiency

Public title

Vitamin D effect on reduction of proteinuria in patients with diabetic nephropathy and vitamin d deficiency

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: having type 2 diabetes; diabetic nephropathy; vitamin D deficiency; GFR> 60 and receiving stable doses of ACE inhibitors or ARBs for 3 months or more. Exclusion criteria: glomerulonephritis; serum phosphorus level greater than 5.2 mg/dL; serum calcium level (adjusted for albumin) greater than 10.0 mg/dL; active malignancy; likelihood of requiring renal replacement therapy within 1 year or uncontrolled hypertension.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences Ethics Committee

Street address
hezar jerib street, Isfahan

City
Isfahan

Postal code

Approval date
2011-07-10, 1390/04/19

Ethics committee reference number
390287

Health conditions studied

1

Description of health condition studied
diabetic nephropathy

ICD-10 code

E11

ICD-10 code description

non insulin dependent diabetes mellitus

Primary outcomes

1

Description

Urine albumin/ creatinin ratio

Timepoint

Before intervention and 3 and 6 months after intervention

Method of measurement

urine Alb/cr (mg/ gr)

Secondary outcomes

empty

Intervention groups

1

Description

intervention: vitamin D pearl; 50000 unit, once weekly to 12 weeks

Category

Treatment - Drugs

2

Description

control: placebo pearl, once weekly to 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Endocrine and Metabolic Diseases Research Center

Full name of responsible person

Nooshin Ahmadi

Street address

Khoram street, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellery for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Azarm
Street address
 Isfahan university of medical sciences
City
 Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Vice chancellery for reaserch, Isfahan University of Medical Sciences
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty