

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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)

###### Phone

+98 31166855555

###### Email address

nooshinahmadi@resident.mui.ac.ir

##### 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

### Contact

**Name of organization / entity**  
Isfahan University of Medical Sciences  
**Full name of responsible person**  
Nooshin Ahmadi  
**Position**  
MD, Resident of internal medicine  
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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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Assistant professor/ endocrinologist  
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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**  
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**Web page address**

## 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*