

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluate the therapeutic effects Sevelamer to reduce blood sugar levels, HbA1c, blood lipids and hs-CRP in patients with diabetic nephropathy

#### Protocol summary

##### Summary

**Objectives:** Evaluate the therapeutic effects of Sevelamer to reduce blood sugar levels, HbA1c, blood lipids and hs-CRP in patients with diabetic nephropathy  
**Design:** Of patients who have inclusion criteria, 30 patients had diabetic nephropathy at stage 2 to 4 and phosphorus in the range of 4 to 6.5 mg/dl of blood and blood sugar of 100 to 400 mg/dl and not receive treatment for hyperphosphatemia are selected. Setting and conduct: At baseline, for all diseases, tests include CBC with diff, BS, BUN, Cr, hs-CRP, HbA1c, Ca, P, TG, Chol, LDL (c), HDL (c) is requested and the results in the questionnaire containing demographic and disease information is recorded. Then, Sevelamer tablets given 800 mg, twice daily, with a meal. After a month of beginning treatment with Sevelamer, CBC with diff, BS, BUN, Cr, Ca, P, hsCRP again requested. At the end of the second month after the beginning of treatment, in addition to the tests conducted in the first month TG, Chol, LDL (c) and HDL (c) is requested. In the third month, HbA1c test in addition to the tests conducted in the first month is requested for patient. The results of this study are analyzed. Before starting the study of all patients, informed consent is obtained. Inclusion criteria: Treated patients due to diabetic nephropathy with 45 years Exclusion criteria: Use of certain medications, presence of associated malignancy

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016100423559N5**  
Registration date: **2016-11-06, 1395/08/16**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-11-06, 1395/08/16

##### Registrant information

###### Name

Somaieh Matin

###### Name of organization / entity

Ardabil University of Medicine Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3373 3011

###### Email address

s.matin@arums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Ardabil University of Medical Sciences

##### Expected recruitment start date

2016-12-21, 1395/10/01

##### Expected recruitment end date

2017-06-20, 1396/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluate the therapeutic effects Sevelamer to reduce blood sugar levels, HbA1c, blood lipids and hs-CRP in patients with diabetic nephropathy

##### Public title

Evaluate the therapeutic effects of Sevelamer to reduce blood sugar levels, HbA1c, blood lipids and hs-CRP in patients with diabetic nephropathy

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Treated patients due to diabetic nephropathy with (6.5% <HbA1C) And Age > 45 years

Exclusion criteria: Use of chemotherapy medications, presence of associated malignancy

### Age

From **45 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### 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

Ardabil University of Medicine Sciences Ethics committee

##### Street address

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

##### City

Ardabil

##### Postal code

53141-56198

#### Approval date

2016-02-25, 1394/12/06

#### Ethics committee reference number

IR.ARUMS.REC.1394.113

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic nephropathy

#### ICD-10 code

N08.3

#### ICD-10 code description

Diabetic nephropathy

## Primary outcomes

### 1

#### Description

Lipid profile

#### Timepoint

At the beginning of study and 1, 2 and 3 months after intervention

#### Method of measurement

Lab.

### 2

#### Description

Cell blood count

#### Timepoint

At the beginning of study and 1, 2 and 3 months after intervention

#### Method of measurement

Lab.

## Secondary outcomes

### 1

#### Description

HbA1c serum level

#### Timepoint

At the beginning of study and 1, 2 and 3 months after intervention

#### Method of measurement

Lab.

## Intervention groups

### 1

#### Description

Treatment intervention with sevelamer (Genian farmed Co) 800 mg two times in day for 3 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Dr. Hossein Fekri

##### Street address

Internal Medicine Department, Imam Khomeini Hospital, Shahid Jeddi street, Ardabil

##### City

Ardabil

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Ardabil University of Medical Sciences

**Full name of responsible person**

Dr Shahram Habibzadeh

**Street address**

Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran

**City**

Ardabil

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Ardabil 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr. Hossein Fekri

**Position**

Internal Medicine Asisstant

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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## Person responsible for updating data

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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*

