

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

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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

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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

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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

