

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study of Sevelamer carbonate effects on hemoglobin A1c, blood glucose and inflammatory factors status in patients with diabetic kidney disease.

Protocol summary

2020-03-11, 1398/12/21

Study aim

The effect of sevelamer on hemoglobin A1c, blood glucose and inflammatory factors in diabetic nephropathy patients

Design

In this study, 24 participants will be selected, who are in the same range of GFR , Proteinuria and BMI .these patients will be selected randomly and divided in two groups.

Settings and conduct

Patients included in this study selected from diabetic nephropathic patients referred to (Imam Ali clinic) in Shahrekord. patients unified before study and randomized in two groups. patients and analysor will be unaware from grouping but researchor will be aware.

Participants/Inclusion and exclusion criteria

1. Age over 18 years 2. Informed patient satisfaction 3. Diabetic nephropathy

Intervention groups

The case group consisted of 24 patients with diabetic nephropathy, who are taken Sevelamer for two months and control group including 24 patients with diabetic nephropathy who are taken Placebo for two month.

Main outcome variables

HBA1C;ESR;CRP;ICAM;VCAM;BS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191111045401N1**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **retrospective**

Last update: **2020-03-11, 1398/12/21**

Update count: **0**

Registration date

Registrant information

Name

Shadi Botshekan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3626 0514

Email address

mosadeghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Sevelamer carbonate effects on hemoglobin A1c, blood glucose and inflammatory factors status in patients with diabetic kidney disease.

Public title

Study of Sevelamer effect on nephropathic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years. Informed patient satisfaction diabetic nephropathy

Exclusion criteria:

Recently received treatment of hyperphosphatemia Have hypophosphatemia or hypercalcemia Pregnancy Known liver disease or active peptic ulcer5 Carbamazepine consumption

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients in Simple randomized method using two card samples that are mentioned A, B letters and divided in two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, according to the use of same capsules in both groups, participants and their carer, as well as assessor, are not aware of the content of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Parastar st. Shahrekord Town

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Approval date

2018-01-04, 1396/10/14

Ethics committee reference number

IR.SKUMS.REC.1397.181

Health conditions studied

1

Description of health condition studied

Diabetic nephropathy

ICD-10 code

E11.21

ICD-10 code description

Type 2 diabetes mellitus with diabetic nephropathy

Primary outcomes

1

Description

BS

Timepoint

Before the beginning of study and two month after using the sevelamer and placebo

Method of measurement

Biochemical assay using BTand optical absorption teqniquis and centrifugation of serum by sampler

2

Description

inflammatory factors(ESR,CRP)

Timepoint

Before the beginning of study and two month after using the sevelamer and placebo

Method of measurement

quantitative qualitative

3

Description

HBA1C

Timepoint

Before the beginning of study and two month after using the sevelamer and placebo

Method of measurement

Using the optical absorption method, we first use a kind of solution that binds to the glycosylated hemoglobin and produced color then we should mesure colored HB

4

Description

inflammatory factor(ICAM,VCAM)

Timepoint

Before the beginning of study and two month after using the sevelamer and placebo

Method of measurement

Elisa(measurement the serum level of Antibody)

Secondary outcomes

1

Description

Degree of systemic inflammation

Timepoint

Befour study and two month after using the drugs

Method of measurement

Quantitative rate of Inflammatory Factor

Intervention groups**1****Description**

Intervention group: diabetic nephropathic patients that given Sevelamer capsule 800 mg 3 times daily for two months before meal.

Category

Prevention

2**Description**

Control group: Diabetic nephropathic patients received placebo three times daily before meal four two months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahrekord Imam Ali clinick

Full name of responsible person

Shadi Botshekan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr.Mohsen Mobini

Street address

shahrekord .Parastar st

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Shahrekord

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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

Shahre-kord 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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Shadi Botshekan

Position

Internal Medicien Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr.Leila Mahmoodnia

Position

Nephrologist

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Shadi Botshekan

Position

Internal Medicien Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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