Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A Comparative study on the effet of Niacin and Sevelamer on decreasing the phosphorous in dialysis patients referring to dialysis department of 5azar medical education center of gorgan in2019(1398)

Protocol summary

Study aim
The effect of nicotinic acid and Renagel and the effect of these two drugs on the reduction of phosphorus in hemodialysis patients
Design
Clinical trials without control group, with parallel groups, non-blind, randomized
Settings and conduct
In the first group, niacin will begin with a dose of 500 mg (100 mg tablets), 3 pills in the morning and 2 pills a night. In the second group, the solaamer starts at a dose of 1600 mg (800 mg capsules) 1 morning and 1 time in the evening.
Participants/Inclusion and exclusion criteria
Aged over 18, satisfaction, serum phosphorus higher than 6 mg / dl, initiation of dialysis for more than 3 months, no change in treatment protocols (calcium and vitamin D compounds), and dialysis protocol over the past 2 weeks
Intervention groups
In the first group, niacin will begin with a dose of 500 mg (100 mg tablets), 3 pills in the morning and 2 pills a night. In the second group, the solaamer starts at a dose of 1600 mg (800 mg capsules) 1 morning and 1 time in the evening. All medications should be taken with food.
Main outcome variables
Phosphorus level Calcium level Duration of dialysis

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190324043106N1**
Registration date: **2022-08-05, 1401/05/14**
Registration timing: **retrospective**
Last update: **2022-08-05, 1401/05/14**
Update count: **0**
Registration date
2022-08-05, 1401/05/14

Registrant information
Name
amirali falahat
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 17 3377 5822
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amirali_aaf1992@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-06-17, 1398/03/27
Expected recruitment end date
2019-07-18, 1398/04/27
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparative study on the effet of Niacin and Sevelamer on decreasing the phosphorous in dialysis patients referring to dialysis department of 5azar medical education center of gorgan in2019(1398)

Public title
A Comparative study on the effet of Niacin and Sevelamer on decreasing the phosphorous in dialysis

patients referring to dialysis department of 5azar medical education center of gorgan in2019(1398)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged over 18 Obtaining consent Serum phosphorus higher than 6 mg / d Start the dialysis period for more than 3 months No change in treatment protocols (calcium and vitamin D compounds) and dialysis protocol over the past 2 weeks

Exclusion criteria:

Patient non-cooperation Inadequate medication compliance Known liver diseases Pregnancy Taking carbamazepine

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **76**

More than 1 sample in each individual

Number of samples in each individual: **2**

blood sample

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: In order to randomize samples, we use a block method with quadrilateral blocks. In this way, one of the following blocks is first selected by accident (for example, with a dice), and according to the order in which those samples are We assign two groups (A for the group receiving Dariviazin and B for the Solamer recipient group). For example, if block 3 is selected and the first one is assigned to the group receiving the drug, and the second and third samples will be allocated to the solamroup recipient group, the fourth will be assigned to the group receiving the drug. Then for four samples, again, a block will be randomly selected. We will allocate it to it and this process will proceed to the end of the sampling.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of golestan university of medical sciences

Street address

gorgan -hircan ave .golestan university of medical sciences

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gorgan

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Golestan

Postal code

61551-49177

Approval date

2019-06-16, 1398/03/26

Ethics committee reference number

IR.GOUMS.REC.1398.074

Health conditions studied

1

Description of health condition studied

Chronic kidney patients undergoing hemodialysis

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

P reduction rate

Timepoint

At the beginning of the study and one month later

Method of measurement

blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Niacin Receiving Group / The first group of patients treated with niacin with a dose of 500 mg per day (100 mg tablets from Abtin Chemical Company); 300 mg in the morning and 200 mg at night with food

Category

Treatment - Drugs

2

Description

Intervention group: Renagel Recipient Group/ The second group of patients treated with sevelamer with a dose of 1600 mg (800 mg capsules of Faran Chem Company); 800 mg in the morning and 800 mg at night with food

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar Hospital

Full name of responsible person

Amirali Falahat

Street address

Fifth Azar Hospital, Fifth Azar Boulevard, Valiasr Square, Gorgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Amirali Falahat

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The level of variables before and after the study / age of the patient / duration of dialysis and sex are informed
When the data will become available and for how long
Start the access period 2 months after printing results
To whom data/document is available
For researchers working in academic and scientific institutions
Under which criteria data/document could be used
request and submission of usage documentation in new studies
From where data/document is obtainable
Golestan University of Medical Sciences / Gorgan - Hirkan Blvd - Golestan University of Medical Sciences / 01732430310 / pr-5azar@goums.ac.ir
What processes are involved for a request to access data/document
The applicant will access within 1 month
Comments