Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of phosphorus-restricted diet with control diet on urine protein excretion in patients with proteinuria

Protocol summary

Study aim

Comparison of the effect of phosphorus-restricted diet with control diet on urine protein excretion in patients with proteinuria

Design

A Randomized controlled clinical trial with parallel design. Total sample size will be 90 and randomization will be done based on the sequences of the random blocks using statistical software.

Settings and conduct

Patients with proteinuria will be evaluated for the study inclusion criteria at nephrology clinic of Kashan University of Medical Sciences. Anthropometric, dietary variables and the ratio of urinary protein to urinary creatinine will be measured at baseline and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages between 18-70 years; Patients with proteinuria in whom the ratio of protein to creatinine in a sample of urine is greater than 0.3 mg/mg; The glomerular filtration rate (eGFR) is more than 15 mL/min/1.73 m2; The serum level of phosphorus should be greater than 3 mg/dL Exclusion criteria: Pregnancy; Lactation; Having diseases such as urinary tract infections, pyelonephritis and kidney stones; consumption of phosphate binders; Taking calcium and vitamin D supplements

Intervention groups

A diet will be designed for the intervention group that its phosphorus content will be limited to 10 to 12 mg/kg/day. For the control group, a control diet will be designed in a way that its contents of energy and other macronutrients will be completely similar to those of the intervention group, however, it will not be limited in terms of phosphorus content. The intervention duration will be 8 weeks for both groups.

Main outcome variables

The primary outcome is a change in the ratio of protein to creatinine excretion in a sample of urine. Secondary outcomes include changes in serum and urinary levels of phosphorus; a change in eGFR; changes in serum levels of fibroblast growth factor 23 (FGF-23)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010333N4**
Registration date: **2019-01-08, 1397/10/18**
Registration timing: **prospective**

Last update: **2019-01-08, 1397/10/18**
Update count: **0**

Registration date

2019-01-08, 1397/10/18

Registrant information

Name

Nasrin Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5562 0608

Email address

sharifi.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-06-05, 1398/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of phosphorus-restricted diet with control diet on urine protein excretion in patients with proteinuria

Public title

The effect of dietary phosphorus reduction on urine protein excretion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with proteinuria in whom the ratio of protein to creatinine in a sample of urine is greater than 0.3 mg/mg The glomerular filtration rate (eGFR) should be greater than 15 mL/min/1.73 m2 The systolic blood pressure should be less than 150 mmHg The serum level of phosphorus should be more than 3 mg/dL Dietary intake of phosphorus should be more than 17-20 mg/kg/day Patients in whom at least 3 months have passed from the onset of anti-proteinuric medications use Patients with proteinuria and diabetes in whom at least 3 months have passed from the onset of taking the glucose lowering drugs or insulin The amount of medications consumed should be constant within 3 months before the start of the study and their type and dosage do not change during the intervention

Exclusion criteria:

Pregnancy Lactation Patients with urinary tract infections Patients with pyelonephritis Patients with kidney stones consumption of various kind of phosphate binders Taking calcium and vitamin D supplements within 3 months before the start of the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups Participants were randomly assigned to intervention or control group in the random blocks based on the random number table.The sequence of permuted blocks was generated with a random number table. An individual with no clinical involvement in the trial, put the lable of intervention or control group in an opaque and sealed envelope based on the random sequence. Then the other person, who was not aware of random sequences and the envelope content, assigned the patients to the intervention or control group.

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 Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Pezeshk Ave., Qotb-e-Ravandi Blvd.

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2018-11-05, 1397/08/14

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.068

Health conditions studied

1

Description of health condition studied

Proteinuria

ICD-10 code

R80.1

ICD-10 code description

Persistent proteinuria, unspecified

Primary outcomes

1

Description

A change in urine protein to creatinine ratio

Timepoint

At baseline and 8 weeks after the start of the phosphorus restricted diet or control diet

Method of measurement

Laboratory clinical kit and analyzer instrument

Secondary outcomes

1

Description
Serum level of phosphorus
Timepoint
At baseline and 8 weeks after the start of the phosphorus restricted diet or control diet
Method of measurement
Laboratory clinical kit and analyzer instrument

2

Description
Urine levels of phosphorus
Timepoint
At baseline and 8 weeks after the start of the phosphorus restricted diet or control diet
Method of measurement
Laboratory clinical kit

3

Description
Serum level of fibroblast growth factor 23 (FGF23)
Timepoint
At baseline and 8 weeks after the start of the phosphorus restricted diet or control diet
Method of measurement
Laboratory clinical kit and analyzer instrument

4

Description
A change in glomerular filtration rate (eGFR)
Timepoint
At baseline and 8 weeks after the start of the phosphorus restricted diet or control diet
Method of measurement
CKD-EPI formula

5

Description
Serum levels of creatinine
Timepoint
At baseline and 8 weeks after the start of the phosphorus restricted diet or control diet
Method of measurement
Laboratory clinical kit and analyzer instrument

6

Description
serum levels of uric acid
Timepoint
At baseline and 8 weeks after the start of the phosphorus restricted diet or control diet
Method of measurement
Laboratory clinical kit and analyzer instrument

Intervention groups

1

Description
Intervention group: A diet will be designed and recommended to intervention group that its phosphorus content will be limited to 10 to 12 mg/kg/day. The intervention duration will be 8 weeks. Also, the intervention group will receive nutritional education in terms of knowing dietary sources of phosphorus and the strategies to reduce their consumption.
Category
Treatment - Other

2

Description
Control group: For control group, a diet will be designed that its contents of energy and other macronutrients are completely similar to those of the intervention group, however, it is not limited in terms of phosphorus content. The intervention duration will be 8 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Nephrology clinic of Shahid Beheshti Hospital
Full name of responsible person
Alireza Soleimani
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Shahid Beheshti Hospital, Pezeshk Ave., Qotb-e-Ravandi Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafshe
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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
Kashan 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
Kashan University of Medical Sciences
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Negar Mozaffari Rad
Position
Graduate student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Fax
Email
sharifi-na@kaums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A portion of the data regarding demographics, anthropometric, and food variables, that are collected at the baseline of the study, and also the information on the main outcome will be shared.

When the data will become available and for how long

The start of the data access period will be one year after the publication of the results.

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

In order to conduct meta analysis studies

From where data/document is obtainable

Nasrin Sharifi, Nutrition Department, School of Medicine, Kashan University of Medical Sciences, Qotbe-e-Ravandi Blvd., Kashan, Iran Postal Code: 88715973474 E-mail: sharifi-na@kaums.ac.ir Tel: 00983155540021 Fax: 00983155620608

What processes are involved for a request to access data/document

An applicant can send a request for a data file by e-mail. After reviewing the request, the data file will be sent to him/her after about three weeks would have passed from the date of the request.

Comments