Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of sevelamer carbonate and sevelamer hydrochloride on blood level of phosphate, Ca, ph, bicarbonate and gastrointestinal complications in patients undergoing maintenance hemodialysis

Protocol summary

Study aim

Comparison of Sevelamer Carbonate and Sevelamer Hydrochloride Effects on the Level of Calcium, Phosphorus, PH, Bicarbonate and Gastrointestinal Complications in Patients Undergoing Maintenance Hemodialysis

Design

Twenty-two samples are included in each group based on the sample size calculated from the results of a pilot study (with a power of 80% and a type 1 error of 5%). Patients will be selected among those in Valiasr Hospital who are under hemodialysis and have entry conditions. Patients will be divided into two groups of intervention with Sevelamer Hydrochloride and Sevelamer carbonate by block randomization method and each participant will be assigned a code to hide the intervention group.

Settings and conduct

In this randomized clinical trial study, patients who undergoing Hemodialysis in Vali Asr Hospital, Zanjan, Iran will participate in the study. Data analyzer and patients will be blinded. blinding were carried out by codding same shape bottles for both drugs.

Participants/Inclusion and exclusion criteria

Patients who undergo three sessions each week for a period of four hours hemodialysis and have a blood phosphorus level greater than 5.5 mg / dL. Exclusion criteria: Patients who have not taken limited Phosphorus diet. Patients who lose their ability to do so during the study Patients who are absent from dialysis session Patients who break their access for some reason Patients who have taken the medication inappropriately Patients with a history of primary hyperparathyroidism or history of parathyroidectomy. Patients with a history of gastrointestinal diseases include peptic ulcer, reflux, and constipation Patients with a history of congestive heart failure (due to electrolyte imbalance) Patients with chronic obstructive pulmonary disease (COPD) (due to acid and basis disorders).

Intervention groups

group 1: 800 mg Sevelamer Carbonate triple time daily with each meal for 1 month. group 2: 800 mg Sevelamer Hydrochloride triple time daily with each meal for 1 month.

Main outcome variables

Blood PH ; Calcium level of serum ; serum phosphorus level ; bicarbonate level of serum ; gastrointestinal complications of each drugs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141016019554N13**
Registration date: **2018-02-17, 1396/11/28**
Registration timing: **retrospective**

Last update: **2018-02-17, 1396/11/28**
Update count: **0**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

Maryam Jameshorani

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-03-21, 1396/01/01
Expected recruitment end date
2017-12-21, 1396/09/30
Actual recruitment start date
2017-03-21, 1396/01/01
Actual recruitment end date
2017-12-21, 1396/09/30
Trial completion date
empty

Scientific title
Comparing the effect of sevelamer carbonate and sevelamer hydrochloride on blood level of phosphate, Ca, ph, bicarbonate and gastrointestinal complications in patients undergoing maintenance hemodialysis

Public title
Comparing the effect of sevelamer carbonate and sevelamer hydrochloride on blood level of phosphate, Ca, ph, bicarbonate and gastrointestinal complications in patients undergoing maintenance hemodialysis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who undergo dialysis three sessions each week for four hours each day. Their blood phosphorus level is higher than 5.5 mg / dL.
Exclusion criteria:
Patients who have not taken limited Phosphorus diet. Patients who lose their ability to participate during the study Patients who are absent from dialysis session Patients who break their access for some reason Patients who have taken the medication inappropriately. Patients with a history of primary hyperparathyroidism or history of parathyroidectomy. Patients with a history of gastrointestinal diseases include peptic ulcer, reflux, and constipation Patients with a history of congestive heart failure (due to electrolyte imbalance) Patients with chronic obstructive pulmonary disease (COPD) (due to acid and basis disorders).
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **44**
Actual sample size reached: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
patients were randomized with block randomization method individually.First, patients are matched in terms of age, sex, and level of phosphorus and other variables listed in the criteria for entry and exit, in 4 blocks, each block containing 11 patients. randomization was done by sealed envelopes by a third blinded person who was not one of the researchers.
Blinding (investigator's opinion)
Single blinded
Blinding description
patients and data analyzer were unaware of the type of drugs. drugs were bottled in coded bottles with only the investigator knowing which code refers to which intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences
Street address
Khorramshahr Street
City
Zanjan
Province
Zanjan
Postal code
4515613113
Approval date
2017-07-04, 1396/04/13
Ethics committee reference number
ZUMS.REC.1396.122

Health conditions studied

1

Description of health condition studied
Calcium, Phosphorus, PH, Bicarbonate and Gastrointestinal Complications in Hemodialysis Patients
ICD-10 code
N18.4
ICD-10 code description
Chronic kidney disease, stage 4 (severe)

Primary outcomes

1

Description

Blood Calcium

Timepoint

at beginning of intervention and 1 month later

Method of measurement

measurement will be carried out by hospital laboratory

2

Description

blood Phosphorus

Timepoint

at beginning of intervention and 1 month later

Method of measurement

measurement will be carried out by hospital laboratory

3

Description

Blood pH

Timepoint

at beginning of intervention and 1 month later

Method of measurement

measurement will be carried out by hospital laboratory

4

Description

Blood Bicarbonate levels

Timepoint

at beginning of intervention and 1 month later

Method of measurement

measurement will be carried out by hospital laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 800 mg Sevelamer Carbonate triple time daily with each meal for 1 month

Category

Treatment - Drugs

2

Description

Intervention group 2: Sevelamer Hydrochloride 800 mg triple daily with each meal for 1 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital in Zanjan

Full name of responsible person

Bahareh Halisalimi

Street address

Dr. Shariati Street

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4515777978

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan 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

Zanjan 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

Zabol University of Medical Sciences

Full name of responsible person

Behrooz Fazeli

Position

Resident of Internal Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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