Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparing the Effect of Sevelamer Hydrochloride and Calcium Carbonate on Serum Level of hs-CRP, Soluable CD-14 and Endotoxin in Hemodialysis Patients

Protocol summary

Study aim

The effect of Sevelamer Hydrochloride and Calcium Carbonate on serum level of hs-CRP, soluble CD-14, and endotoxin in hemodialysis patients will be studied.

Design

Randomized clinical trial on two parallel groups, without blinding, phase 4 on 50 patients, which will use Rand list software for randomization.

Settings and conduct

The present study will be performed on hemodialysis patients referred to Imam Reza Hospital of Tabriz University of Medical Sciences. Patients will be randomly divided into two equal groups and will be intervened for two months. At the end of the study, the levels of endotoxin, sCD-14 and hs-CRP will be examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria are age over 18 years old, end-stage renal disease, hemodialysis for more than three months and indication for treatment with phosphate binders. Also non-inclusion criteria are impossibility of alternative treatment with Sevelamer Hydrochloride or Calcium Carbonate, history of any substance abuse, history of immunological diseases, any cancer, recent active infection, history of previous kidney transplantation and history of receiving immunosuppressive therapy.

Intervention groups

Patients in group A will receive Sevelamer Hydrochloride 800 mg tablets 3 times daily with meals for 2 months and group B patients will receive Calcium Carbonate1000 mg tablets 3 times daily with meals for 2 months.

Main outcome variables

The primary outcomes of the present study are serum levels of endotoxin; sCD-14 and hs-CRP. Also the secondary outcome of the present study is possible side effects of each drug.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200724048193N1**
Registration date: **2020-11-15, 1399/08/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-15, 1399/08/25**
Update count: **0**

Registration date

2020-11-15, 1399/08/25

Registrant information

Name

Shabnam Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3380 5677

Email address

salehish@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the Effect of Sevelamer Hydrochloride and Calcium Carbonate on Serum Level of hs-CRP, Soluable CD-14 and Endotoxin in Hemodialysis Patients

Public title
Comparing the Effect of Sevelamer Hydrochloride and Calcium Carbonate on Serum Level of Inflammatory Markers in Hemodialysis Patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ESRD Indication of treatment with phosphate binders Hemodialysis preformation for more than three months
Exclusion criteria:
Impossibility of alternative treatment with Sevelamer Hydrochloride or Calcium Carbonate Cigarette, alcohol and drug abuse History of immunological diseases Any type of cancer Recent active infection Previous kidney transplant history History of receiving immunosuppressive treatment

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done using Rand list software version 1.2 based on patients' file numbers and creating a random number table. Patients will be randomly divided into two equal groups and randomly assigned to the Sevelamer Hydrochloride or Calcium Carbonate 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 Tabriz University of Medical Sciences
Street address
6th floor, No.116, 7th Sahand Alley, Sahand Blvd, Tabriz, Iran.
City
Tabriz
Province
East Azarbaijan
Postal code
5168643619

Approval date
2015-08-24, 1394/06/02

Ethics committee reference number
TBZMED.REC.1394.470

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease

ICD-10 code
I13.11

ICD-10 code description
Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease

Primary outcomes

1

Description
Endotoxin

Timepoint
At the beginning of the study and two months after starting treatment

Method of measurement
Serum level measurement

2

Description
high-sensitivity C-reactive protein

Timepoint
At the beginning of the study and two months after starting treatment

Method of measurement
Serum level measurement

3

Description
Soluable CD-14

Timepoint
At the beginning of the study and two months after starting treatment

Method of measurement
Serum level measurement

Secondary outcomes

1

Description
Possible side effects
Timepoint
Two months after starting treatment
Method of measurement
Assessment and questioning of the patient

Intervention groups

1

Description
Intervention group: Receiving 800 mg Sevelamer Hydrochloride tablets product by Faran Shimi pharmaceutical 3 times a day with meal for 2 months
Category
Treatment - Drugs

2

Description
Intervention group: Receiving 500 mg Calcium Carbonate tablets product by Jalinous pharmaceutical at dose of 1000 mg 3 times a day with meal for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Shabnam Salehi
Street address
Emam Reza Hospital, Daneshgah Street, Daneshgah Square
City
Tabriz
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East Azarbaijan
Postal code
5166614756
Phone
+98 41 3337 3966
Email
salehish@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad samiei
Street address
Third floor of Tabriz University of Medical Sciences Central Building, Golgasht Street, Tabriz
City
Tabriz
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East Azarbaijan
Postal code
5166614766
Phone
+98 41 3335 7310
Email
Samiei.moh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Shabnam Salehi
Position
Nephrologist
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Emam Reza Hospital, Daneshgah Street, Daneshgah Square
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Shabnam Salehi

Position
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Person responsible for updating data

Contact

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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
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
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available