

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, Soluble 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 Carbonate 1000 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, Soluble 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**

Soluble 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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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

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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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Person responsible for scientific inquiries

Contact

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Tabriz University of Medical Sciences

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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