

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Sevelamer and Calcium carbonat on magnesium serum level in hemodialyzed patients referring to hemodialysis center of Kosar hospital in Semnan in 2018-9

Protocol summary

Study aim

comparison of sevelamer and calcium carbonate on magnesium serum level in hemodialyzed patients

Design

Two arm parallel group randomised trial with non blinded postoperative care and outcome assessment

Settings and conduct

Randomized trial in hemodialyzed patients referring to hemodialysis center of Kosar hospital in Semnan in 2018

Participants/Inclusion and exclusion criteria

Entrance: Patients who ESRD and treated with hemodialysis 3 times in week in 3 months and have phosphorus level upper than 5.4 mg/dl Exit: Patients who have associated diseases e.g acute heart or liver diseases; history of recent diarrhea; history of Ileostomia or colostomia; history of major GI surgery; patients who treated with cyclosporin, aminoglycosids, amphotrysin B, furasemid, Thiazids or Proton pump inhibitors; patients who have hypercalcemia

Intervention groups

Comparison of sevelamer and calcium carbonate

Main outcome variables

Magnesium serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180831040912N1**

Registration date: **2018-10-25, 1397/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-25, 1397/08/03**

Update count: **0**

Registration date

2018-10-25, 1397/08/03

Registrant information

Name

elahe jandaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3334 1157

Email address

dr.ejandaghi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sevelamer and Calcium carbonat on magnesium serum level in hemodialyzed patients referring to hemodialysis center of Kosar hospital in Semnan in 2018-9

Public title

Comparison of Sevelamer and Calcium carbonat on magnesium serum level in hemodialyzed patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ESRD patients who need hemodialysis 3 times week in 3

months Serum Phosphorus level >5.4mg/dl

Exclusion criteria:

Those who did not complete the consent Associated disease e.g acute heart & liver diseases History of recent Diarrhea History of Ileostomia or colostomia History of major GI surgery Patients who treated with Cyclosporin, Aminoglycosids, Amphotricin B, Furasemid and Thiazids Patients who treated with PPI Patients who had hypercalcemia

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Random sequence

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 Semnan University of Medical Sciences

Street address

Kosar Hospital, Basidj Blvd.

City

semnan

Province

Semnan

Postal code

3514618653

Approval date

2018-02-13, 1396/11/24

Ethics committee reference number

IR.SEMUMS.REC.1397.076

Health conditions studied

1

Description of health condition studied

ESRD patients who hemodialyzed

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

Magnesium serum level

Timepoint

Before study and 3 months after treatment

Method of measurement

Photometric method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sevelamer with brand name Foseal manufactured in Emcure pharmaceutical LTD. India 800 mg start with one tablet daily up to 3 tablet depend on calcium and phosphorus level

Category

Treatment - Drugs

2

Description

Intervention group: calcium carbonate manufactured in Saponin pharmaceutical Co.. I. R.Iran 500 mg start with one tablet daily up to 3 tablet depend on calcium and phosphorus level

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital

Full name of responsible person

Elahe Jandaghi

Street address

Kosar hospital, Basidj Blvd.

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3142 2410

Email

dr.ejandaghi@gmail.com

Web page address

<http://kosarhos.semums.ac.ir/index.jsp>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaie

Street address

Semnan University of Medical Sciences, Basidj Blvd.

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rds@semums.ac.ir

Web page address

<http://rtvc.semums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Elahe Jandaghi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Elahe Jandaghi

Position

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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