

# 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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**Province**

Semnan

**Postal code**

3519899951

**Phone**

+98 23 3341 0221

**Email**

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

**Street address**

Kosar hospital, Basidj Blvd.

**City**

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**Phone**

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**Email**

dr.ejandaghi@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Elahe Jandaghi

**Position**

Assistant professor

**Latest degree**

Specialist

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## Person responsible for updating data

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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