Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Randomized clinical trial of comparing hemodialysis with high-flux and low-flux filters in controlling hyperphosphatemia in patients with end stage renal disease

Protocol summary

Summary

(1) Objectives: Our aim in this study is to compare the effects of using high-flux and low-flux dialysis on controlling hyperphosphatemia in patients with end stage renal disease. (2) Design: Sixty patients under dialysis from both genders will be included in a double blind randomized clinical trial. Patients will be divided randomly into two groups of high-flux and low-flux filters after qualifying the inclusion and exclusion criteria and obtaining the informed consent. (3) Setting and conduct: All of the patients had phosphate more than 6 mg/dl, although they were receiving medical treatment. Patients in high-flux group will be dialysed for two months with high-flux filters and patients in low-flux groups dialysed for two months with low-flux filters. Phosphate, lipid profile and hemoglobin will be measure before and after the two months period. Inclusion criteria: Age between 10-85 years old; patient is hemodialyzed for at least 6 months. Exclusion criteria: Patients using phosphate binder drugs irregularly; patients who are attending for hemodialysis irregularly. (4) Interventions: Sixty patients assigned into two groups of 30; hwmodialysis with low-flux filter and hemodialysis with high-flux filter and finally phosphate, lipid profile and hemoglobin will be measure before and after the two months period. (5) Main outcome measures: Serum phosphate level, lipid profile and hemoglobin which will be measured before starting the study and two months after hemodialysis.

General information

Acronym

ESRD

IRCT registration information

IRCT registration number: **IRCT201306136123N2**
Registration date: **2013-06-28, 1392/04/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-06-28, 1392/04/07

Registrant information

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Seyed Sadraddin Rasi Hashemi
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Scienses

Expected recruitment start date

2012-12-25, 1391/10/05

Expected recruitment end date

2013-05-26, 1392/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial of comparing hemodialysis with high-flux and low-flux filters in controlling hyperphosphatemia in patients with end stage renal

disease

Public title
Comparison of two kinds of hemodialysis filters in controlling serum phosphate
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age between 10-85 years old; patient is hemodialyzed for at least 6 months. Exclusion criteria: Patients using phosphate binder drugs irregularly; patients who are attending for hemodialysis irregularly.
Age
From **10 years** old to **85 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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
Ethics committee، Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz
City
Tabriz
Postal code
Approval date
2011-03-26, 1390/01/06
Ethics committee reference number
90106

Health conditions studied

1

Description of health condition studied
End stage renal disease treated with dialysis
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

2

Description of health condition studied
Instrumentation used in hemodialysis
ICD-10 code
Z49.0
ICD-10 code description
Preparatory care for dialysis

Primary outcomes

1

Description
Serum phosphate level
Timepoint
Before starting the study and two months after hemodialysis
Method of measurement
Laboratory kit

2

Description
hemoglobin
Timepoint
Before starting the study and two months after hemodialysis
Method of measurement
Laboratory kit

3

Description
Lipid profile
Timepoint
Before starting the study and two months after hemodialysis
Method of measurement
Laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description
In low-flux group, patients will be hemodialysed with low-flux filter for two months
Category
Treatment - Devices

2

Description
In high-flux group, patients will be hemodialysed with high-flux filter for two months
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Hesam Rasoul Amini
Street address
Department of Internal diseases, Imam Reza Hospital, Daneshgah Square, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Seyyed Kazem Shakouri
Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz
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Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
University of Medical Sciences
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Hesam Rasoul Amini
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty