

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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

Name

Seyed Sadraddin Rasi Hashemi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 3966

Email address

rashashemis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

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

Full name of responsible person

Hesam Rasoul Amini

Position

General Practitioner

Other areas of specialty/work

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Web page address

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