

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of High Flux versus Low Flux membranes on the level of parathyroid hormone in patients with secondary hyperparathyroidism undergoing chronic dialysis

Protocol summary

Summary

The purpose of this study was to compare the effectiveness of the High Flux and Low Flux membranes on parathyroid hormone serum level in patients with secondary hyperparathyroidism undergoing chronic dialysis. Total of 40 patients referring to Tohid Hospital dialysis center in 2014 who passed inclusion criteria of the study were selected and using the table of random numbers randomly divided into two groups of 20. The control group with Low Flux membrane and the intervention group with High Flux membrane. In order to double blind the study, a colleague who had not sensitivity to study took the blood samples, he also sent the samples to lab. Inclusion criteria included high level serum of parathyroid hormone (greater than 300pg / dl), performing dialysis by fixed means, dialysis three times a week for four hours, the patient should be at least 6 months on dialysis program, previous use of the Low Flux membrane, bearing on dialysis, age greater than 18 years, the ability to participate in the study and exclusion criteria included; patients with acute renal failure, patients with poor vascular access that may affect their quality of dialysis, age less than 18 years, the continued lack of patient cooperation, discontinuation of dialysis for any reason, being dialysis by High Flux membrane previously. In the beginning of the study for both groups blood samples were taken before dialysis. Laboratory evaluation included serum levels of phosphorus and parathyroid hormone were conducted. The use of Low Flux and High Flux membranes in the both groups continued for three months. Laboratory evaluation included serum levels of parathyroid hormone and phosphorus was repeated again in the end of the study for both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121712789N10**

Registration date: **2015-05-29, 1394/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-29, 1394/03/08

Registrant information

Name

Masoud Rasolabady

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kurdistan University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title Comparing the effect of High Flux versus Low Flux membranes on the level of parathyroid hormone in patients with secondary hyperparathyroidism undergoing chronic dialysis	Name of ethics committee Ethics Committee of Kurdistan University of Medical Sciences
Public title Comparing the High Flux versus Low Flux membranes	Street address Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran
Purpose Treatment	City Sanandaj
Inclusion/Exclusion criteria Inclusion criteria included high level serum of parathyroid hormone (greater than 300pg / dl), performing dialysis by fixed means, dialysis three times a week for four hours, the patient should be at least 6 months on dialysis program, previous use of the Low Flux membrane, bearing on dialysis, age greater than 18 years, the ability to participate in the study. Exclusion criteria included; patients with acute renal failure, patients with poor vascular access that may affect their quality of dialysis , age less than 18 years, the continued lack of patient cooperation, discontinuation of dialysis for any reason, being dialysis by High Flux membrane previously	Postal code Approval date 2014-09-03, 1393/06/12
Age From 18 years old to 65 years old	Ethics committee reference number 14/21678
Gender Both	Health conditions studied
Phase 3	1
Groups that have been masked No information	Description of health condition studied Secondary hyperparathyroidism, not elsewhere classified
Sample size Target sample size: 40	ICD-10 code N25.8
Randomization (investigator's opinion) Randomized	ICD-10 code description secondary hyperparathyroidism of renal origin
Randomization description	
Blinding (investigator's opinion) Double blinded	Primary outcomes
Blinding description	1
Placebo Not used	Description level serum of parathyroid hormone
Assignment Parallel	Timepoint Beginning of the study - Three months after the study
Other design features To make the study double blind, blood sample taking and sending the blood samples to laboratory was done by one of the colleagues working in dialysis ward. Also patients were not aware of their grouping and the kind of membrane used for their hemodialysis.	Method of measurement ELISA method
Secondary Ids empty	Secondary outcomes
Ethics committees	1
1	Description serum levels of phosphorus
Ethics committee	Timepoint Beginning of the study -Three months after the study
	Method of measurement The Prestige 24i Automated Analyzer
	2
	Description Hemodialysis Adequacy
	Timepoint Beginning of the study -Three months after the study
	Method of measurement kt/v method
	Intervention groups
	1
	Description

In the intervention group, patients who have been on dialysis with Low Flux membrane for three years would be on dialysis for three months with High Flux membrane.

Category

Treatment - Other

2

Description

In the control group, patients who previously had been dialyzed by Low Flux membrane for three years would be dialyzed again for three months using Low Flux membrane .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Hospital

Full name of responsible person

Rasol Azimi

Street address

Tohid Hospital, Basij Sq., Geriashan St., Sanandaj, Iran

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Kurdistan University of Medical Sciences

Full name of responsible person

Fardin Gharibi

Street address

Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran

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Sanandaj

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, Kurdistan 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

Kurdistan University of Medical Sciences

Full name of responsible person

Rasol Azimi

Position

Resident of Internal Medicine

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