

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of High Flux with Low Flux membrane in Patient's Comfort, Level of Electrolytes and Clearances of Articles in Hemodialysis' Patients

Protocol summary

Summary

In a clinical trial (cross over method) 30 hemodialysis' patients will be study during two hemodialysis sessions by High Flux with Low Flux filters to compare the effects of these filters in the clearance of articles, Level of Electrolytes and in Patient's Comfort. Including criteria are: fistula or arteriovenous graft vascular access; three weekly dialysis sessions; four hours per dialysis session; coping bearing in dialysis sessions; at least six months of dialysis experience; consciousness and the ability to fully participate in the project; no history of heart disease, pulmonary disease and other acute disease; need to less than three liters of ultrafiltration and hemoglobin greater than 8 mg/dl. The incidence of complications in hemodialysis (blood pressure changes, nausea, vomiting, itching, muscle aches and headaches) with a list of Czech research and questionnaires are recorded. During the second session, sampling of the arterial line before and after dialysis For Evaluation amounts of sodium, potassium, phosphorus, urea and creatinine are done. During the second stage, the same 30 patients are done hemodialysis with filter High Flux two session. All procedures and measurements is the same . Hemodialysis procedure has proved in two steps. If patients with severe hypotension, severe complications of hemodialysis, no patient discontinued dialysis and cause allergic reactions, patients are excluded. Results between the two phases, the rate of clearance of particles , electrolyte and complications of hemodialysis between the two filters, are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106094505N3**
Registration date: **2011-07-10, 1390/04/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-07-10, 1390/04/19

Registrant information

Name

Rasool Kavyannejad

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 5322 3828

Email address

rasol.kavian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vise chancellor for research and technology Hamedan university of medical sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2011-08-23, 1390/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of High Flux with Low Flux membrane in Patient's Comfort, Level of Electrolytes and

Public title

Comparison the effect of High Flux with Low Flux membrane in Patient's Comfort, Level of Electrolytes and Clearances of Articles in Hemodialysis' Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: An arteriovenous fistula or graft; three dialysis sessions weekly; Dialysis four hours per session; tolerate dialysis sessions; History of dialysis for at least six months; Full alertness and ability to project participation; Hello not for dialysis patients; Dialysis performed by the machine fixed; No history of heart disease; acute pulmonary disease; Having less than three liters of ultrafiltration; hemoglobin more than 8 mg per dL; Non-antibiotic drugs to be false values for creatinine such as Trimetoprim Exclusion criteria: severe hypotension; severe complications of hemodialysis; lack of patient cooperation; patient discontinuation Dialysis and allergic reactions can be excluded.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences & Health Services

Street address

Mahdye street

City

Hamedan

Postal code**Approval date****Health conditions studied****1****Description of health condition studied**

End stage renal disease

ICD-10 code

N18.0

ICD-10 code description

End-stage renal disease

Primary outcomes**1****Description**

systolic and diastolic blood pressure

Timepoint

per a hours

Method of measurement

sphygmomanometer

2**Description**

clearance Na,K,P,BUN,Cr

Timepoint

before and after hemodialysis

Method of measurement

Using Electrolyte Machine

Secondary outcomes**1****Description**

itch

Timepoint

during and 48 hours after hemodyalisis

Method of measurement

VAS

2**Description**

nauseas

Timepoint

during and 48 hours after hemodialysis

Method of measurement

VAS measure

3**Description**

vomiting

Timepoint

during and 48 hours after hemodialysis

Method of measurement

Four state criteria

4

Description

headache

Timepoint

Four state criteria

Method of measurement

VAS measure

5

Description

Muscle pain

Timepoint

during and 48 hours after hemodialysis

Method of measurement

VAS measure

Intervention groups

1

Description

Selected patients in a Phase ,2 session of dialysis with low-flow filter, is performed. During the second session, a blood sample to check the values of variables before and after hemodialysis is done. Complication rate during each hemodialysis session and 48 hours later is measured

Category

Treatment - Other

2

Description

In other step,the same Selected patients, 2 session of dialysis with High-flow filter, is performed. During the second session, a blood sample to check the values of variables before and after hemodialysis is done. Complication rate during each hemodialysis session and 48 hours later is measured

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital Hemodialysis Center

Full name of responsible person

Mino Razeghi

Street address

Shahid Beheshti Hospital, Eram Square, Hamedan, Iran

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology Hamedan university of medical sciences

Full name of responsible person

Ali Ghaleiha

Street address

Hamedan university of medical sciences, Mahdye Street, Hamedan, Iran

City

Hamedan

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 and technology Hamedan 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

Hamadan University of Medical Sciences & Health Services

Full name of responsible person

Rasool Kavyannejad

Position

MSc student of critical care nursing

Other areas of specialty/work

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Person responsible for scientific

inquiries

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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

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University of Medical Sciences & Health Services

Full name of responsible person