Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Rasool Kavyannejad
Name of organization / entity
Hamedan University of Medical Sciences
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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

Clearances of Articles in Hemodialysis' Patients

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
2011-06-12, 1390/03/22
Ethics committee reference number
112/9/35/16

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 neasure

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 tecnology 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 tecnology 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
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Person responsible for scientific

inquiries

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Person responsible for updating data

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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