Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The efects of stepwise sodium and ultrafiltration profiles and dialysis solution fow rate profile on dialysis adequacy of hemodialysis patients

Protocol summary

Summary

Background: Insufficiency of dialysis is one of the main factors for mortality of patients undergoing hemodialysis. The methods enhancing the adequacy of dialysis in these patients are of great importance due to improving the quality of life. The present study has been conducted with the aim of investigating the effect of Stepwise Sodium and Ultra filtration Profiles and Dialysis Solution Flow Rate Profile on Dialysis Adequacy. Methods: This study is a cross over design in which 32 patients from two hemodialysis centers in Isfahan were evaluated. Hemodialysis patients sessions as follows: 4 routine 4Stepwise Sodium and UF Profiles and 4 Dialysis Solution Flow Rate Profile in each session the KT/V was measured by OCM. The results were analyzed by the variance analysis statistical test with the repetitive observations and paired T test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305073560N3**
Registration date: **2013-07-28, 1392/05/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-07-28, 1392/05/06

Registrant information

Name
Nahid Shahgholian
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-05-26, 1392/03/05

Expected recruitment end date

2013-06-26, 1392/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efects of stepwise sodium and ultrafiltration profiles and dialysis solution fow rate profile on dialysis adequacy of hemodialysis patients

Public title

Iincrease in adequacy of dialysis in haemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion creteria: undergoing hemodialysis over 3 month; undergoing hemodialysis two times a week with bicarbonat. Exclusion creterion: intradialytic hypotension.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences,Hezarjerib Street , Isfahan, Iran.
City
Isfahan University of Medical Sciences ,Hezar jarib street,Isfahan,Iran
Postal code
Approval date
2012-11-22, 1391/09/02
Ethics committee reference number
392068

Health conditions studied

1

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

Primary outcomes

1

Description
Dialysis Adequacy
Timepoint
After each session intervention
Method of measurement
OCM

Secondary outcomes

empty

Intervention groups

1

Description
Group 1:4 Stepwise Dialysis Solution Flow Rate Profile (Dialysis Solution Flow Rate Profile 800mil/min-500mil/min)-4Stepwise Sodium and UF Profiles (Sodium 164 mmol/lit-138 mmol/lit and proportionate UF-4Stepwise routine (Sodium 138 mmol/lit with UF stable and Solution Flow Rate 500mil/min)
Category
Treatment - Other

2

Description
Group 2: 4 Stepwise routine (Sodium 138 mmol/lit with UF stable and Solution Flow Rate 500mil/min)- 4 Stepwise Sodium and UF Profiles (Sodium 164 mmol/lit-138 mmol/lit and proportionate UF)- 4 Stepwise Dialysis Solution Flow Rate Profile(Dialysis Solution Flow Rate Profile 800mil/min-500mil/min)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mohammadrasolallah center Mobarakeh
Full name of responsible person
Elahe Esmeilzadeh
Street address
Mohammadrasolallah center-Safaeieh-Mobarakeh
City
Mobarakeh

2

Recruitment center
Name of recruitment center
Shohadaye Lenjan Hospital
Full name of responsible person
Shahin Bayat
Street address
Shohadaye lenjan Hospital-Zarin Shahr-Iran
City
Zarin Shahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Maryam Kianpour
Street address
School of Nursing and Midwifery- Isfahan University of Medical Sciences-Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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
Isfahan University of Medical Sciences
Full name of responsible person
Nahid Shahgholian
Position
MSc/Academic member
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Person responsible for updating data

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School of Nursing and Midwifery, Isfahan University of Medical Sciences ,Hezar jerib Street, Isfahan, Iran
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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