

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effects of stepwise sodium and ultrafiltration profiles and dialysis solution flow 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)

Phone

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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 effects of stepwise sodium and ultrafiltration profiles and dialysis solution flow rate profile on dialysis adequacy of hemodialysis patients

Public title

Increase in adequacy of dialysis in haemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: undergoing hemodialysis over 3 month; undergoing hemodialysis two times a week with bicarbonat. Exclusion criterion: 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)-4 Stepwise Sodium and UF Profiles (Sodium 164 mmol/lit-138 mmol/lit and proportionate UF)-4 Stepwise 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 addressSchool 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

Other areas of specialty/work**Street address**School of Nursing and Midwifery- Isfahan University of
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Mojgan Mortazavi

Position

Assistant professor

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Position

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Fax**Email****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*