Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Combined effect of sodium and ultrafiltration profiles on some of the common complications during hemodialysis

Protocol summary

Summary

This research is a clinical trial which will be performed in Latin square and single-blind method. The purpose of this research is to determine the combined effect of sodium and ultrafiltration profiles on some of the common complications during hemodialysis. The samples are hemodialysis patients in Panje Azar Hospital of Gorgan, Iran, who had hypotension for more than three sessions during last month. Other inclusion criteria are age of 18-75, hemodialysis for more than three months and three times a week with a solution of sodium bicarbonate. The patients have systolic blood pressure <100 mm Hg before starting dialysis. Patients with complications which would be studied in this project (cramps, nausea, vomiting and headache) and patients who recieve analgesic, anti-hypertensive and anti-spasmodic are not included. The samples, 44 patients, are selected by accessible sampling method, and randomly allocated to four groups of 11 members. In each of the groups, one specific protocol for hemodialysis is performed. 1: Linear sodium dialysate and constant ultrafiltration. 2: Constant sodium dialysate and gradient ultrafiltration. 3: Linear sodium dialysate and gradient ultrafiltration. 4 (standard hemodialysis): Constant sodium dialysate and constant ultrafiltration. In every session, blood pressure is monitored five times. Any muscle cramps, nausea, vomiting and headache are recorded. GAMRO AK96 hemodialysis machine are used for all samples.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111208140N1**
Registration date: **2012-03-05, 1390/12/15**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-03-05, 1390/12/15

Registrant information

Name
Einollah Mollaei
Name of organization / entity
Golestan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 17 1442 6900
Email address
mollaei@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Golestan University of Medical Sciences

Expected recruitment start date

2012-01-14, 1390/10/24

Expected recruitment end date

2012-04-12, 1391/01/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combined effect of sodium and ultrafiltration profiles on some of the common complications during hemodialysis

Public title

The effect of sodium and ultrafiltration profiles on preventing from the complications made during hemodialysis

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: hemodialysis patients in Panje Azar Hospital of Gorgan, who have: 1- hypotension for more than three sessions during last month (20 percent of the sessions). 2- Age of 18-75 years. 3- hemodialysis for more than three months. 4- Dialysis for three times a week with a solution of sodium bicarbonate. 5- End-stage renal diseases. Exclusion criteria: The patients, 1- Before starting dialysis, having systolic blood pressure of below 100 mm Hg. 2- Patients with complications studied in this project (cramps, nausea, vomiting and headache). 3- Administered analgesic, anti-hypertensive and anti-spasmodic, four hours before of dialysis.
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Golestan University of Medical Sciences
Street address
Kilometer 2 Gorgan-Sari
City
Gorgan
Postal code
Approval date
2011-10-30, 1390/08/08
Ethics committee reference number
1390883

Health conditions studied

1

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

Primary outcomes

1

Description
Blood pressure
Timepoint
pre, intra & post dialysis
Method of measurement
Blood pressure based on mm Hg, monitoring by Gambro AK96 dialysis machine

2

Description
Muscle cramps
Timepoint
pre, intra & post dialysis
Method of measurement
checklist

3

Description
nausea & vomiting
Timepoint
pre, intra & post dialysis
Method of measurement
with checklist

4

Description
headache
Timepoint
pre, intra & post dialysis
Method of measurement
with checklist

Secondary outcomes

1

Description
Urea
Timepoint
pre & post dialysis
Method of measurement
Laboratory method

2

Description
sodium plasma

Timepoint
pre & post dialysis
Method of measurement
Laboratory method

3

Description
plasma osmolality
Timepoint
pre & post dialysis
Method of measurement
Laboratory method

Intervention groups

1

Description
For each group in this research, four different hemodialysis protocols are implemented. These protocols are as follows: Protocol 1: Linear Sodium Dialysate (150 - 138mEq/L) and constant Ultrafiltration. Protocol 2: Constant Sodium Dialysate (140 mEq/L) and gradient ultrafiltration. Protocol 3: Linear Sodium Dialysate (150 - 138 mEq/L) and gradient ultrafiltration. Protocol 4: (standard hemodialysis) = Constant Sodium Dialysate (140 mEq/L) and constant Ultrafiltration. Linear Sodium Dialysate: In the first hour of the dialysis the amount of Sodium dialysate is 150mEq/L, then is gradually decreasing by 4mEq/L per hour. In the last hour of the dialysis, it reaches 138mEq/L. Gradient Ultrafiltration: Two-thirds of the fluid acquired between 2 dialysis sessions is removed during the first two hours of the dialysis and the reset in the last two hours. This protocol can be programmed on Gambro AK96 dialysis machine. Constant Ultrafiltration: The excessive fluid acquired between hemodialysis is determined. This fluid is taken back in equal volumes in each hour of a four -hour dialysis session. Constant Sodium Dialysate: During a four -hour -dialysis session, sodium dialysate is kept in140 mEq/L. For any patients, six hemodialysis sessions are considered for each of the protocols. For group A, protocols, 1-2-3 and 4 run respectively.
Category
Prevention

2

Description
For Group B, protocols, 2-3-4 and 1 run respectively.
Category
Prevention

3

Description
For Group C, protocols, 3-4-1 and 2 run respectively.
Category
Prevention

4

Description
For Group D, protocols, 4-1-2 and 3 run respectively.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis therapy centre, 5 Azar hospital
Full name of responsible person
Einollah Mollaei
Street address
City
Gorgan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Golestan University of Medical Sciences
Full name of responsible person
Mohsen Aarabi
Street address
Kilometer 2 Gorgan Sari
City
Gorgan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Golestan 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
Golestan University of Medical Sciences
Full name of responsible person
Einollah Mollaei
Position
Assistant Professor, Department of Medical Surgical Nursing

Other areas of specialty/work
Street address
Golestan University of Medical Sciences , Kilometer 2 Goran-Sari
City
Gorgan
Postal code
Phone
+98 17 1442 6900
Fax
Email
Mollaei@goums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Golestan University of Medical Sciences
Full name of responsible person
Einollah Mollaei
Position
Assistant Professor, Department of Medical Surgical Nursing
Other areas of specialty/work
Street address
Golestan University of Medical Sciences, Kilometer 2 Goran-Sari
City
Gorgan
Postal code
Phone
+98 17 1442 6900
Fax
Email
Mollaei@goums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Golestan University of Medical Sciences
Full name of responsible person
Einollah Mollaei
Position
Other areas of specialty/work
Street address
City
Gorgan
Postal code
Phone
Fax
Email
Mollaei@goums.ac.ir
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