

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 receive 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)

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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 in 140 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

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Kilometer 2 Gorgan Sari

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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

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Position

Assistant Professor, Department of Medical Surgical Nursing

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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