Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of sodium profile and temperature on blood pressure fluctuations of patients in hemodialysis section of Imam Hossein hospital in Shahrood ،2013

Protocol summary

Summary

This research is a clinical trial which will be performed in cross-over and single-blind method. The purpose of this research is to determine the effect of sodium and temperature profiles on blood pressure fluctuations during hemodialysis. The samples are hemodialysis patients in Imam Hossein Shahrood, Iran . inclusion criteria are age of 18-75, hemodialysis for more than six months and three times a week with a solution of sodium bicarbonate. The patients have systolic blood pressure <100 mm Hg before starting dialysis. and patients who receive , anti-hypertensive and blood transfusion are not included. The samples, 80 patients, are selected by accessible sampling method, and randomly allocated to four groups of members. In each of the groups, one specific protocol for hemodialysis is performed. 1: Standard sodium dialysate and standard temperature. 2: Standard sodium dialysate and low temperature. 3: line sodium dialysate and Standard temperature. 4 :High sodium and low temperature. In every session, blood pressure is monitored five times. Any muscle cramps, nausea, vomiting and headache are recorded. Fresenius hemodialysis machine are used for all samples.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050613248N1**
Registration date: **2013-11-30, 1392/09/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-11-30, 1392/09/09

Registrant information

Name
Marzieh Hossein Saedee
Name of organization / entity
Tehran medical Branch of Islamic Azad university
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran medical Branch of Islamic Azad University

Expected recruitment start date

2013-11-01, 1392/08/10

Expected recruitment end date

2014-02-01, 1392/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sodium profile and temperature on blood pressure fluctuations of patients in hemodialysis section of Imam Hossein hospital in Shahrood ،2013

Public title

The effect of sodium profile change and temperature on preventing from the blood pressure fluctuations during hemodialysis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :the patients are between 18t-75 years old؛ they have Chronic Kidney disease ؛ patients must have medical records in hospital and three sessions dialysis weekly؛ Exclusion criteria: The patients with specific infections disease history؛ Acquired immune deficiency syndrome - coagulopathy- poor nutrition and patients who are using antihypertensive drugs and eating large meals plus patients who have received blood products on hemodialysis sessions؛ The patients with chronic diseases who have hypertension during hemodialysis have also been excluded.

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: **80**

Randomization (investigator's opinion)
N/A

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
Shahrood University of Medical Sciences

Street address
university of medical science , Haft-e-tir square , Shahrood

City
shahrood

Postal code
3614773955

Approval date
2013-05-26, 1392/03/05

Ethics committee reference number
920/04

Health conditions studied

1

Description of health condition studied
Chronic kidney desease

ICD-10 code
N18.5

ICD-10 code description
End stage kidney disease

Primary outcomes

1

Description
BLOOD PRESSURE

Timepoint
Before, during and after the study

Method of measurement
mm/hg

Secondary outcomes

empty

Intervention groups

1

Description
For each group in this research, four different hemodialysis protocols are implemented. These protocols are as follows: Protocol A:Standard Sodium Dialysate and Standard Temprature. Protocol B: Standard Sodium Dialysate and low temprature. Protocol C: Linear Sodium Dialysate (150 - 138 mEq/L) andStandard temprature. Protocol D: Linear Sodium Dialysate (150 mEq/L-138) and low temprature. Linear Sodium Dialysate: In the first hour of the dialysis the amount of Sodium dialysate is 150mEq/L, then is gradually decreasing in per hour. In the last hour of the dialysis, it reaches 138mEq/L. The low temprature is 35 ° C and standard temprature is 37° C.For any patients, three hemodialysis sessions are considered for each of the protocols.Standard sodium dialysate: During the 3-hour dialysis session, dialysate sodium of 140 mEq /L is maintained. For group A, protocols, ADBC run respectively

Category
Prevention

2

Description
For Group B, protocols, BACD run respectively.

Category
Prevention

3

Description
For Group C, protocols, CBDA run respectively

Category
Prevention

4

Description
For Group D, protocols, DCAB run respectively.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital, Shahrood
Full name of responsible person
Marzieh Hossein Saedee
Street address
Hemodyalysis of Imam Hossein Hospital, Shahrood
City
Dameghan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran medical Branch of Islamic azad university
Full name of responsible person
Marzieh hossein Saedee Graduate student of nursing
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Damghan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran medical Branch of Islamic azad university
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
Tehran medical Branch of Islamic azad university
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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