

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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

Country

Iran (Islamic Republic of)

Phone

+98 23 2524 3517

Email address

parisan.saeidi@yahoo.com

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 disease

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 Temperature. Protocol B: Standard Sodium Dialysate and low temperature. Protocol C: Linear Sodium Dialysate (150 - 138 mEq/L) andStandard temperature. Protocol D: Linear Sodium Dialysate (150 mEq/L-138) and low temperature. 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 temperature is 35 ° C and standard temperature 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

Hemodialysis 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

Street address

Tehran medical Branch of Islamic azad university ,
Khagh ani Ave, shariati st, Tehran

City

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

Full name of responsible person

Marzieh hossein Saedee

Position

Graduate student of nursing

Other areas of specialty/work

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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