

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effects of linear sodium - ultrafiltration profile on patient tolerance during hemodialysis, in Hemodialysis patients Hamadan's Besat Hospital 1392.

Protocol summary

Summary

Objective: To determine the effect of sodium linear profile - ultrafiltration during hemodialysis on patient tolerance. Study design: crossover. Population of patients admitted to hospital dialysis center in Hamedan besat. Primary criteria: patients 18-75 years old, more than three months Hemodialysis being overweight at 1-4 kg between dialysis, dialysis two or three times a week with a solution of sodium bicarbonate solution, night predialysis blood pressure-lowering drugs are not used. patients with severe anemia (Hb <8) they may not. Main exclusion criteria: severe cardiac and pulmonary disorders , unstable heart muscle death and during dialysis, blood pressure is high enough to lead to discontinuation of dialysis, blood transfusion and other solutions, enhancing the patient's blood volume. analysis is not. samples: 30 patients. intervention or interventions: Case study on any of the sample profile linear sodium - ultrafiltration and routine dialysis will be performed. intervention for each of the randomly dialysis sessions using profiles Linear sodium - ultrafiltration is carried out, and two meeting routine dialysis are. variables five times (before , the first hour, second hour, third hour and 5 minutes after hemodialysis) with both methods of measurement are . primary outcome was a consequence: changes during hemodialysis patients intolerant

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072814194N1**

Registration date: **2013-08-26, 1392/06/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-08-26, 1392/06/04

Registrant information

Name

Azam Farmani

Name of organization / entity

Hamedan University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research & technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-08-30, 1392/06/08

Expected recruitment end date

2013-10-10, 1392/07/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of linear sodium - ultrafiltration profile on patient tolerance during hemodialysis, in Hemodialysis patients Hamadan's Besat Hospital 1392.

Public title

Effects of profile on patient tolerance during hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria for this study included : Patients 18-75 years old ; Over 3 months of hemodialysis; 1-4 kg weight gain between dialysis ; Patients with end-stage renal disease ; Dialysis two or three times a week with a solution of sodium bicarbonate should be done; No night predialysis blood pressure -lowering drugs are not used ; Heart disease - specific diseases such as heart muscle death or have a pacemaker ; With severe anemia (Hb <8) do not ; According to medical diabetic neuropathy (due to orthostatic hypotension in these patients) are not. Exclusion criteria : Heart and lung disorders; unstable heart muscle death and during dialysis ; Lack of patient cooperation ; Low blood pressure is high enough to lead to discontinuation of dialysis ; if Anti hypertensive drugs in patients on dialysis or had consumed the night before, or before a dialysis session should eat foods high in volume, it is not the meeting to analyze the data; Hypertensive patients after transfusion of blood and other solutions will not increase blood volume analysis .

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

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

Ethic committee of Hamadan university of medical sciences

Street address

Hamadan university of medical sciences, Shahid Fahmideh st, Hamadan

City

Hamadan

Postal code

۶۵۱۷۶۱۹۶۵۱

Approval date

2013-07-27, 1392/05/05

Ethics committee reference number

16/359/1378/پ

Health conditions studied

1

Description of health condition studied

Hemodialysis patient

ICD-10 code

N18.5

ICD-10 code description

End stage kidney disease: on dialysis

Primary outcomes

1

Description

Blood pressure

Timepoint

Before hemodialysis, the first , second, third and fifth minutes after hemodialysis.

Method of measurement

Mercury manometer

2

Description

Muscle Cramp

Timepoint

Before hemodialysis, the first , second, third and fifth minutes after hemodialysis.

Method of measurement

Visual Analog Scale

3

Description

Comfort

Timepoint

After each dialysis session

Method of measurement

Visual Comfort Scale Kolkaba

Secondary outcomes

empty

Intervention groups

1

Description

In this study, the typical profile of linear sodium - ultrafiltration is performed . Purpose of linear sodium dialysate is sodium dialysate during the hours of the first treatment, dialysis, 146 mmol/ l started and then gradually each time reduced dialysis until the last hour to 138 mmol l appears. Purpose of linear ultrafiltration is

Two-thirds of the fluid that accumulates between dialysis sessions during the first 2 hours of dialysis treatment and the remaining third in the last 2 hours, the patient's blood is removed from the line by the dialysis machine.

Category

Prevention

2

Description

In the example that was made to the profile , the dialysis procedure is performed . During the procedure, the dialysate sodium concentration of 138 mmol l first and last dialysis treatment on the ultrafiltration rate remains constant and does not change

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan's Besat Hospital

Full name of responsible person

Azam Farmani, MSc Student in Critical care nursing

Street address

Besat Hospital, Motahari blv, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research & technology, Hamadan university of medical sciences

Full name of responsible person

D.r Haider Toilani

Street address

Hamadan university of medical sciences, Shahid Fahmideh st, Hamadan

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research & technology, Hamadan 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

Hamadan university of medical sciences

Full name of responsible person

Azam Farmani

Position

MSc Student in Critical care nursing

Other areas of specialty/work

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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