Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of ascending-descending profile of ultrafiltration along with sodium profile on systolic and diastolic blood pressure during the dialysis process in patients undergoing hemodialysis treatment.

Protocol summary

Study aim
The effect of ascending-descending profile of ultrafiltration along with sodium profile on blood pressure of hemodialysis patients

Design
The clinical trial is cross-over, with parallel groups, double-blind and with a sample size of 30

Settings and conduct
For each of the patients, six sessions with the routine method (in which the sodium concentration of the dialysis solution remained constant at 143 mmol/liter from the beginning to the end of the dialysis and the amount of ultrafiltration did not change), and six sessions with a combination of sodium profile and profile 1 Ultrafiltration of the B-Brown Dialog Positive 1 device (ascending-descending profile of ultrafiltration) of hemodialysis will be performed in the dialysis department of the 9th Day Hospital of Torbat Heydarieh city.

Participants/Inclusion and exclusion criteria
Inclusion criteria: with chronic renal failure. Exclusion criteria: Unwillingness to participate in the study

Intervention groups
This study will be conducted cross-sectionally and during two periods. Each of the patients underwent six sessions with the routine method (in which the sodium concentration of the dialysis solution remained constant at 143 mmol/liter from the beginning to the end of dialysis and the amount of ultrafiltration did not change), and six sessions with a combination of sodium profile and ultrafiltration profile 1. B-Brown Dialog Positive 1 device (ascending-descending ultrafiltration profile) will perform hemodialysis. Also, 4 wash-out sessions are planned for patients.

Main outcome variables
Blood pressure

General information

Reason for update
The sample size was changed due to reaching the required sample size.

Acronym

IRCT registration information
IRCT registration number: **IRCT20180429039463N5**
Registration date: **2023-01-07, 1401/10/17**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-07, 1402/10/17**
Update count: **1**

Registration date
2023-01-07, 1401/10/17

Registrant information

Name
mohammad namazinia

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-29, 1401/10/08

Expected recruitment end date
2023-03-01, 1401/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of ascending-descending profile of ultrafiltration along with sodium profile on systolic and diastolic blood pressure during the dialysis process in patients undergoing hemodialysis treatment.

Public title
Effect of dialysis machine profile on blood pressure
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18-75 suffering from end-stage renal disease (GFR less than 10% in non-diabetics and non-elderly and GFR less than 15% in diabetics and the elderly) Being on hemodialysis for more than six months Dialysis three times a week with sodium bicarbonate buffer solution Not having specific cardiovascular problems such as heart attack, atrial fibrillation or using a pacemaker Not having severe anemia
Exclusion criteria:
Unwillingness to participate in the study Try to get a vein or needle more than twice in each vascular pathway Fistula failure
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, patients will be informed that they will participate in a study, but they will not know that they are in the control group or in the intervention group.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Torbat Heydariyeh University of Medical Sciences
Street address
Torbat Heydariyeh University of Medical Sciences, Razi St.
City
Torbat Heydariyeh
Province
Razavi Khorasan
Postal code
9519633787
Approval date
2022-12-26, 1401/10/05
Ethics committee reference number
IR.THUMS.REC.1401.031

Health conditions studied

1

Description of health condition studied
Chronic renal failure
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Blood pressure
Timepoint
In this study, blood pressure is measured before dialysis, the first hour, the second hour, the third hour, the fourth hour, and after each dialysis session.
Method of measurement
Each of the samples rested in the supine position after baring the hand with the hand of the sphygmomanometer while the cuff of the device was closed at least 2.5 to 3 cm above the elbow and was measured and recorded.

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: In the ascending-descending ultrafiltration profile mode, the duration of dialysis is routinely considered to be 4 hours. Ultrafiltration in this hemodialysis program is divided into three phases (ascending, intermediate and venular). In the ascending phase, 25.5% of the patient's total weight is taken with a low UF rate. In the middle phase, there is an aggressive phase that takes 51.2% of the patient's weight, which is

the maximum UF rate in this phase. In the descending phase, 23.6% of the total weight of the patient is taken, and the UF rate of this phase is also low.

Category

N/A

2

Description

Control group: In routine mode without ultrafiltration profile, the patient's weight is divided every hour, weighing is taken to balance. For example, in a patient who has 4 liters of excess weight during 4 hours of hemodialysis, the ultrafiltration rate is 1000 ml per hour.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nohome day Hospital, Torbat Heydarieh University of Medical Sciences

Full name of responsible person

Mohammad Namazinia

Street address

Torbat Heydariyeh University of Medical Sciences Building., Razi St., Ferdawsi St.

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95195481$6

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mnamazi99@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rezaei Manesh

Street address

Torbat Heydariyeh University of Medical Sciences Building., Razi St., Ferdawsi St

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Torbate-Heidaria University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Mohammad Namazinia

Position

Member of the faculty of Torbat Heydarieh University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main consequence after being unidentified will be shared

When the data will become available and for how long

Start the access period 6 months after Publish results

To whom data/document is available

Everyone

Under which criteria data/document could be used

The results obtained in this study can be used without restriction by researchers.

From where data/document is obtainable

Referring to Torbat Heidarieh Nursing and Midwifery Faculty

What processes are involved for a request to access data/document

After sending the email to the person responsible for the response process begins.

Comments