

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effect of liner, step-wise and functional ultrafiltration profiling on hypotension during hemodialysis in patients with chronic renal failure

Protocol summary

Study aim

Determining the effect of linear, step-wise and functional ultrafiltration profiling on hypotension during dialysis in patients with chronic renal failure

Design

clinical trial with a control group in format of Latin square design , one-sided blind, randomized

Settings and conduct

The intervention site is hemodialysis. unites. For all patients, 4 different ultrafiltration protocols will be implemented. Protocols 1 include linear profiles, protocol 2: stack profiles, protocol 3: functional profiles, protocol 4: fixed ultrafiltration profiles, each of which will run for each group for 2 weeks. For each protocol, 6 hemodialysis sessions are considered and patients undergo hemodialysis 3 times a week and 4 hours each time. Patients' blood pressure will be controlled at each session in 5 times: before hemodialysis, at the first hour, second hour, third hour and after hemodialysis in the half-sitting position of the patient's arm.

Participants/Inclusion and exclusion criteria

Getting end stage renal failure Hemoglobin>10 History of dialysis 3 months at least Dialysis 3 times a week Systolic blood pressure above 100 mm Hg before dialysis Not use anti-hypertensive medication 4 hours before dialysis Exclusion criteria: Classes 3 and 4 of Heart Failure Hepatic Impairment

Intervention groups

32 patients will be randomly blocked into four groups. Each block contains the letters A, B, C, and D, which patients will randomly place in these blocks. Then, the four groups will receive four different treatment protocols. Subjects in Group A will first receive Protocol 1, then 2, 3, and 4. Group B receives protocol 2, then 3, 4 and 1. Group C will also receive protocols 3, 4, 1 and 2, respectively. Group D will receive protocol 4, then 3, 2, and 1.

Main outcome variables

Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140802018649N4**

Registration date: **2019-07-08, 1398/04/17**

Registration timing: **prospective**

Last update: **2019-07-08, 1398/04/17**

Update count: **0**

Registration date

2019-07-08, 1398/04/17

Registrant information

Name

Khadijeh Yazdi

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 6900

Email address

yazdi@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-20, 1398/04/29

Expected recruitment end date

2019-09-13, 1398/06/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of liner, step-wise and functional ultrafiltration profiling on hypotension during hemodialysis in patients with chronic renal failure

Public title

Effect of ultrafiltration profiling on hypotension during hemodialysis

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

getting end stage renal failure hemoglobin>10 history of dialysis 3 months at least Dialysis 3 times a week Systolic blood pressure above 100 mm Hg before dialysis Not use anti-hypertensive medication 4 hours before dialysis

Exclusion criteria:

Classes 3 and 4 of Heart Failure Hepatic Impairment

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

32 patients will be randomly blocked into four groups. Each block contains the letters A, B, C, and D, which patients will randomly place in these blocks. Then, the four groups will receive four different treatment protocols. Subjects in Group A will first receive Protocol 1, then 2, 3, and 4. Group B receives protocol 2, then 3, 4 and 1. Group C will also receive protocols 3, 4, 1 and 2, respectively. Group D will receive protocol 4, then 3, 2, and 1.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient does not know that will be in which one of the four groups of treatment protocols.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Booyeh Nursing and Midwifery Faculty, Falsafi educational Campus, Beginning of Shast Kola Road, Gorgan

City

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Postal code

4934174515

Approval date

2019-02-17, 1397/11/28

Ethics committee reference number

IR.GOUMS.REC.1398.002

Health conditions studied**1****Description of health condition studied**

Chronic kidney disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease

Primary outcomes**1****Description**

Blood pressure

Timepoint

before hemodialysis, 1 hour, 2 hours, 3 hours and after hemodialysis

Method of measurement

sphygmomanometer

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: group will receive ultrafiltration profiles in the form of protocols, each protocol will be implemented for a period of 2 weeks and overall 8 weeks as below. At first, Protocol 1 include linear profiles of ultrafiltration, then protocol 2 including stepwise profiles, protocol 3 including functional profiles of ultrafiltration and protocol 4 include of fixed ultrafiltration, each one for 2 weeks.

Category

Treatment - Other

2

Description

Intervention group2: group will receive ultrafiltration profiles in the form of protocols, each protocol will be implemented for a period of 2 weeks and overall 8 weeks as below. First, protocol 2 included a stepwise profile, then protocol 3: functional profile, protocol 4 include of fixed ultrafiltration, and protocol 1 containing linear ultrafiltration, each one for 2 weeks.

Category

Treatment - Other

3

Description

Intervention group3: group will receive ultrafiltration profiles in the form of protocols, each protocol will be implemented for a period of 2 weeks and overall 8 weeks as below. First, protocol 3 includes functional profiles, then protocol 4 including fixed ultrafiltration, next protocol 1 of linear ultrafiltration, and at the end protocol 2, including stepwise ultrafiltration profiles, each one for 2 weeks.

Category

Treatment - Other

4

Description

Intervention group: group will receive ultrafiltration profiles in the form of protocols, each protocol will be implemented for a period of 2 weeks and overall 8 weeks as below. First, protocol 4 including fixed ultrafiltration, then protocol 1 of linear ultrafiltration, next protocol 2, including stepwise ultrafiltration and at the end protocol 3 includes functional profiles, each one for 2 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Payambar Azam Hospital

Full name of responsible person

Fatemeh Barani

Street address

Beginning of the road Incheh Broun, Gonbad Kavoods

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Web page address

http://goums.ac.ir/index.php?slc_lang=fa&sid=130

2

Recruitment center

Name of recruitment center

Shahid Motahhri hospital

Full name of responsible person

Enseah Yousofzadeh

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East of Taleghani Street, Student Blvd. intersection, Shahid Motahari Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Reza Honarvar

Street address

Shast Kola road, Falsafi campus, Deputy of research and technology

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Phone

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Web page address

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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

Gorgan 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

amirkhanloo@goums.ac.ir

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Person responsible for general inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Khadijeh Yazdi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Saeid Amir Khanloo

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The protocol and analyzing method and the results will be published in the form of a report of the project and the scientific paper

When the data will become available and for how

long

3 months after submitting the results to the relevant organization

To whom data/document is available

Academic researchers and for nurses who are working in hemodialysis units.

Under which criteria data/document could be used

Just to improve the provision of patient care and

research work

From where data/document is obtainable

Khadijeh Yazdi

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

The request is sent by email to be answered by the research team as soon as possible after review.

Comments