# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

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

**Public title**
Effect of ultrafiltration profiling on hypotention 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**
Gorgan

**Province**
Golestan

**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 stapwise 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 stapwise 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 Kavoos
**City**
Gonbad Kavoos
**Province**
Golestan
**Postal code**
4934174515
**Phone**
+98 17 3328 0121
**Email**
yazdi@goums.ac.ir
**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**
Enseaeh Yousofzadeh
**Street address**
East of Taleghani Street, Student Blvd. intersection, Shahid Motahari Hospital
**City**
Gonbad
**Province**
Golestan
**Postal code**
4934174515
**Phone**
+98 17 3355 1111
**Email**
yazdi@goums.ac.ir
**Web page address**
http://goums.ac.ir/index.php?sid=79&slc_lang=fa

## 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
**City**
Gorgan
**Province**
Golestan
**Postal code**
4934174515
**Phone**
+98 17 3245 1660
**Email**
yazdi@goums.ac.ir
**Web page address**
http://goums.ac.ir/index.php?slc_lang=fa&sid=12
**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

## 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
**Street address**
Shast Kola road, Falsafi Campus, booyeh Nursing and Midwifery school
**City**
Gorgan
**Province**
Golestan
**Postal code**
4934174515
**Phone**
+98 17 3245 6900
**Fax**
+98 17 3242 5171
**Email**
yazdi@goums.ac.ir
**Web page address**
http://goums.ac.ir/

## 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**
Internal Medicine
**Street address**
Sast Kola Road, Fasafi educational campus, Medical Faculty
**City**
Gorgan
**Province**
Golestan
**Postal code**
4934174515
**Phone**
+98 17 3245 1442
**Fax**
+98 17 3242 5171
**Email**
amirkhanloo@goums.ac.ir
**Web page address**
http://goums.ac.ir/cv/899/dramirkhanloo/

## Person responsible for updating data

**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
**Street address**
Sast Kola road, Falsafi educational campus, Nursing and Midwifery Faculty
**City**
Gorgan
**Province**
Golestan
**Postal code**
4934174515
**Phone**
+98 17 3245 6900
**Fax**
+98 17 3242 5171
**Email**
yazdi@goums.ac.ir
**Web page address**
http://goums.ac.ir/cv/2403/drkhyazdi/

## 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**