

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of ultrafiltration profile on blood pressure control in patients undergoing hemodialysis

Protocol summary

Study aim

The effect of ultrafiltration profile on blood pressure control in patients undergoing hemodialysis

Design

cross over clinical trial with convenience sampling and single blind study on approximate 30 patients

Settings and conduct

Study in the field of hemodialysis will be performed in Shahid Beheshti hospital in Hamedan to investigate the effect of profiling on ultrafiltration. the type of profile that will apply to patients with intradialytic hypertension is interval with negative slope. Research sessions in each patient are 6 sessions, of which 3 sessions are with intervention and the other 3 sessions are without intervention. The study is single blind that patients after getting information about the research and accepting to attend the study they will not be informed of the routine or intervention of hemodialysis session.

Participants/Inclusion and exclusion criteria

Hemodialysis patients with intradialytic hypertension:
Hemodialysis patients with normal blood pressure during dialysis and intradialytic hypotension.

Intervention groups

Apply ultrafiltration profile with interval and negative slope

Main outcome variables

Increase or decrease in patients blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220206053954N1**

Registration date: **2022-03-18, 1400/12/27**

Registration timing: **prospective**

Last update: **2022-03-18, 1400/12/27**

Update count: **0**

Registration date

2022-03-18, 1400/12/27

Registrant information

Name

Morteza Haghighi enayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3429 2379

Email address

morteza21.h@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-04-18, 1401/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ultrafiltration profile on blood pressure control in patients undergoing hemodialysis

Public title

The effect of ultrafiltration profile on blood pressure control in hemodialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

hemodialysis patients with intradialytic hypertension

Exclusion criteria:

Hemodialysis patients with cardiovascular disorders.
Hemodialysis patients who are younger than 18 and older than 80 years. Patients with no consent.

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: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

After explaining to patients about the intervention and getting their permission, 6 sessions of hemodialysis will be performed by the researcher. Three sessions will be with intervention, and three sessions will be done routinely. Patients will not be informed that in which sessions intervention will take place.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hamedan University of Medical science

Street address

No. 54, shahid ghafarian Ave, Mirzadeh eshghi Blvd.

City

Hamedan

Province

Hamadan

Postal code

6715911111

Approval date

2022-01-23, 1400/11/03

Ethics committee reference number

IR.UMSHA.REC.1400.844

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

Intradialytic hypertension among chronic hemodialysis patients

ICD-10 code

S37.0

ICD-10 code description

Injury of kidney

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

The rate of increase in blood pressure

Timepoint

Before starting hemodialysis, 1 hour later, 2 hour later, 3 hour later and 15 minutes after the end of the session

Method of measurement

Analog blood pressure monitor

Secondary outcomes

empty

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

Intervention group: Apply interval profile with negative slope for ultrafiltration. In three sessions of hemodialysis, which is applied from the beginning of hemodialysis until separation from the machine. Blood pressure changes measured before starting hemodialysis, every hour during hemodialysis, and a quarter after completion. Na = 138 mEq adjusted, pump speed 250 and solution temperature 36.5 ° C adjusted during hemodialysis

Category

Prevention

2**Description**

Control group: Hemodialysis patients are hemodialyzed in the next three sessions without profile application in their ultrafiltration with Na = 138 mEq and pump speed of 250 and solution temperature 36.5 ° C adjusted during hemodialysis.

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti hospital

Full name of responsible person

Seyed Reza Bourzo

Street address

No.54, Shahid Ghafarian Ave, Mirzadeh Eshghi Ave.

City

Hamedan

Province

Hamadan

Postal code

6715911111

Phone

+98 83 3429 2379

Email

Morteza21.h@gmail.com

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

No.54, Shahid Ghafarian Ave., Mirzadeh Eshghi Ave.

City

Hamedan

Province

Hamadan

Postal code

6715911111

Phone

+98 83 3429 2379

Email

Borzoureza@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Seyed Reza Bourzo

Street address

No.54, Shahid Ghafarian Ave., Mirzadeh Eshghi Ave.

City

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Province

Hamadan

Postal code

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Email

Morteza21.h@gmail.com

Grant name

Research assistance of Hamedan University of Medical Science

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Seyed Reza Bourzo

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Morteza Haghighi enayat

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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No 54, Shahid ghafarian Ave, Mirzade eshghi Ave.

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Province

Hamadan

Postal code

6715911111

Phone

+98 83 3429 2379

Fax**Email**

morteza21.h@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Morteza Haghighi enayat

Position

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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

Data related to patients cardiovascular disease history along with the evaluation of the main outcome of the study

When the data will become available and for how long

Access period starts 3 months after the results are published

To whom data/document is available

All people working in medical universities and medical centers

Under which criteria data/document could be used

In order to develop science and solve medical problem

From where data/document is obtainable

Refer to Hamedan University of medical science or the researcher's email

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

After 3 weeks of sending an email to the researcher and explaining the reason of access

Comments