

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of care educational intervention on the adequacy and complications during hemodialysis

Protocol summary

Study aim

Determining the effect of educational care educational intervention on the adequacy and prevention of complications during hemodialysis

Design

A clinical trial with a control group, a blind strain, on 88 patients, which will be conducted by lottery in the form of single or double visits.

Settings and conduct

Research location: Dialysis center of Imam Hossein (AS) hospital, Malayer city. The samples are divided into two intervention groups (visitors on even or odd days) and the control group (visitors on even or odd days) which are selected through lottery and blinding will be in the field of statistical analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age above 18 years Absence of mental problems, blindness, deafness Not having a history of known muscle diseases Hemodialysis 3 times a week, duration of dialysis 3:30 and more Exclusion criteria: Clotting of the patient's blood during dialysis Blood transfusion during hemodialysis Receiving medication for low blood pressure and muscle cramps

Intervention groups

Control group: completion of demographic information questionnaire and examination of hemodialysis complications and hemodialysis adequacy. intervention group: 1: Training on diet and taking personal medications and weight control between dialysis sessions 2: Use of sodium profile and ultrafiltration profile and temperature profile during hemodialysis 3: Set ultrafiltration to a maximum of 13cc/kg/h 4: Lower limb priority in case of blood pressure less than 90 mm Hg 5: Lower massage in the third hour of dialysis 6: Taking 5 cc blood samples before and after dialysis to measure hemodialysis adequacy

Main outcome variables

Blood pressure drop, adrenal congestion, adequacy of hemodialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231010059684N1**

Registration date: **2023-11-19, 1402/08/28**

Registration timing: **prospective**

Last update: **2023-11-19, 1402/08/28**

Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

Kazem Keyhanfar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8670 5503

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-26, 1402/09/05

Expected recruitment end date

2023-12-01, 1402/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of care educational intervention on the adequacy and complications during hemodialysis

Public title

The effect of care educational intervention on the adequacy and complications during hemodialysis

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Desire to cooperate and participate in research Age above 18 years Hemodialysis 3 times a week The duration of dialysis is 3:30 and more

Exclusion criteria:

Receiving medication for low blood pressure and muscle cramps Having a history of known muscle diseases Having mental problems, blindness, deafness

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Not randomized

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

Single blinded

Blinding description

In the present study, blinding will be done only in the context of the statistical analyst, in such a way that the statistical analyst will not be aware of the allocation of patients in the intervention and control groups, and the control and intervention groups will be marked with a code of one and two, so that only the researcher from the control group and have knowledge of intervention

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Behorzi Education Center, Behir Alley, Sohrab Zand

Street

City

Hamedan

Province

Hamadan

Postal code

6573139435

Approval date

2023-10-10, 1402/07/18

Ethics committee reference number

IR.ARAKMU.REC.1402.139

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

Hemodialysis

ICD-10 code

Y84.1

ICD-10 code description

Kidney dialysis

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

blood pressure less than 90 mm Hg during hemodialysis

Timepoint

Measurement of blood pressure drop in the first, second and third hours of dialysis.

Method of measurement

Mercury sphygmomanometer

2**Description**

muscle cramps during hemodialysis.

Timepoint

Measuring the occurrence of muscle cream in the first, second and third hours of dialysis

Method of measurement

check list

3**Description**

adequacy of hemodialysis

Timepoint

Measurement of hemodialysis adequacy before and after intervention

Method of measurement

Daggerdas formula

Secondary outcomes

empty

Intervention groups

1

Description

intervention group:1: Training on diet and taking personal medications and weight control between dialysis sessions2: Use of sodium profile and ultrafiltration profile and temperature profile during hemodialysis3: Set ultrafiltration to a maximum of 13cc/kg/h4: Lower limb priority in case of blood pressure less than 90 mm Hg5: Lower massage in the third hour of dialysis6: Taking 5 cc blood samples before and after dialysis to measure hemodialysis adequacy

Category

Prevention

2

Description

Control group: Control group: In the control group, no care training will be given. This group will undergo dialysis according to the normal routine, and 5 cc of blood will be taken before and after dialysis to measure the adequacy of dialysis.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Malayer Hospital

Full name of responsible person

Keyhanfar Kazem

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Web page address

<https://imamhossein-hosp.umsha.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology of Arak University of Medical Sciences

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Alam El Hadi St., Khilban Shahid Shiroudi

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Keyhanfar Kazem

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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