Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone
+98 21 8670 5503

Email address
k.keyhanfar@arakmu.ac.ir

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

Street address
Imam Hossein Hospital, Nurse Street

City
Malayer

Province
Hamadan

Postal code
6571961441

Phone
+98 81 3222 0001

Email
Imamhossein_hosp@umsha.ac.ir

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

Street address
Alam El Hadi St., Khilban Shahid Shiroudi

City
Arak

Province
Markazi

Postal code
۳۸۱۹۶۹۳۳۶۵

Phone
+98 86 3313 6055

Email
it@arakmu.ac.ir

Web page address
https://www.arakmu.ac.ir

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
Nursery

Street address
Behorzi Education Center, Behiyar Alley, Sohrab Zand St

City
Malayer

Province
Hamadan

Postal code
6573139435

Phone
0098 81 2411755

Email
K.keyhanfar@Arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Hamdani Behzad
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Arak Medical Sciences
City
Arak
Province
Markazi
Postal code
۳۸۱۹۶۹۳۳۶۵
Phone
+98 86 3313 6055
Email
Hamedanibehzad166@yahoo.com

Person responsible for updating data

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
Nursery
Street address
Imam Hossein Hospital
City
Malayer
Province
Hamadan
Postal code
6517953371
Phone
0098 81 2411755
Email
K.keyhanfar@Arakmu.ac.ir

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