Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The study of effect lowering the dialysate temperature on hemodynamic indicators and dialysis efficiency of the diabetic patients in aliabn abitalb (AS) hospital of zahedan university of medical sciences in 2018

Protocol summary

Study aim

1. Determination and comparison the mean of systolic blood pressure in the routine and cold dialysis methods, before dialysis, at 1, 2, 3 hours during dialysis and after dialysis. 2. Determination and comparison of diastolic blood pressure in the routine and cold dialysis methods, before dialysis, at 1, 2, 3 hours during dialysis and after dialysis. 3. Determination and comparison of arterial blood pressure in the routine and cold dialysis methods, before dialysis, at 1, 2, 3 hours during dialysis and after dialysis. 4. Determination and comparison of mean Heart rate in the routine and cold dialysis methods, before dialysis, at 1, 2, 3 during dialysis and after dialysis. 5. Determination and comparison the temperature of patients undergoing dialysis treatment in the routine and cold dialysis methods, before and after hemodialysis. 6. Determination and comparison the adequacy of dialysis in patients undergoing hemodialysis in the routine and cold dialysis methods, before and after hemodialysis.

Design

In this study, 32 hemodialysis patients are selected availably according to the available entry conditions, which are referred to hemodialysis department of Ali ebn Abitalib Hospital in Zahedan. The study phase does not apply to this study.

Settings and conduct

In this study, 32 hemodialysis patients are selected availably and non-randomly, with inclusion criteria, who are referred to hemodialysis unit of Ali ebn Abitalib hospital in Zahedan. Essential descriptions of how the study is conducted and the purpose of the study is given to patients who are asked to read and sign the written consent form and then with regard to age, gender, occupation, education, and compliance with medical ethics and safety, we complete the demographic information of the patients. Patients undergo hemodialysis in two sessions, once with a cold solution (36 ° C) and the next session with a routine or conventional solution (37 ° C). The hemodialysis variables except for temperature are the same in both cases. The hemoglobin is warmed up to 36.5 to 37.5 ° C (normal range) before the hemodialysis. All patients have one type of dialyser and a dialysis solution (with bicarbonate) will be used. In the beginning, all machines are verified for the correctness of the function. In order to harmonize the conditions in this study, the rate of fluid harvesting for each patient is determined based on the weight difference before the patient's pure weight loss. The ambient temperature (23 ° C) is controlled throughout the study. The concentration of sodium fluid in dialysis is constant in all sessions. Blindness does not apply to this study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having a history of hemodialysis at least three months before the study, not taking low blood pressure medications, patients weighing less than 2 kg, those who had reached a systolic pressure of less than 90 mm Hg in their previous dialysis sessions and experienced related symptoms with it, having no severe anemia (>8Hb) , no malignancy, no thyroid abnormalities. Exclusion criteria: Patient's death, dialysis immaturity with a cold solution (in case of very severe chills), food and fluid intake exceeds the amount prescribed during dialysis, unwillingness to continue to participate in the study.

Intervention groups

The study is conducted in 2018. All patients who undergo dialysis 3 times a week and 3-4 hours each are included in the study. The hemodialysis fluid flow rate is constant at 500 mm / min with a Fresenius 4008-B apparatus and the same ultrafiltration with the same filtration rate, which is constant for all patients during the study. The fluid withdrawal rate for each patient was calculated before the dialysis weight was calculated with the patient's dry weight and the machine's total weight The accuracy and accuracy of the device, blood pressure,

and blood pressure of 8 patients are measured 5 times in a 5-minute sitting period. The systolic and diastolic blood pressure of the patients is measured by a digital doped barometric In the early stages of dialysis, during the first, second and third days of dialysis, and immediately after the end of dialysis, the patient's heart rate is measured at the same time as the blood pressure and the same device. Before and after After each dialysis session, the temperature of the mufflers is measured and recorded. In addition, if the patient complains at least one of the symptoms of hypotension, such as muscle cramps, nausea, vomiting, fatigue and dizziness, his blood pressure will be measured at the same time. The number of times the pressure drop and the changes in pressure and number of actions are necessary. In order to heal, the difference in blood pressure is the difference between the systolic and diastolic blood pressure during dialysis, as well as systolic and diastolic blood pressure, and the onset of dialysis. The mean arterial pressure (MAP) is calculated from the sum of systolic and dihidrostheol divided by 3 times. The patient's time is hypotension, with systolic blood pressure lower than 90 mm Hg. In patients whose baseline blood pressure is 100-90 mm Hg , A 25% drop or a decrease of 20 mm in excess of systolic pressure as hypotension. Dialysis adequacy means that dialysis takes up 70% or more of blood urea over a 4-hour dialysis period, and subsequent administration of dialysis should be based on a higher or at least 70% withdrawal rate. The procedure is that in the final dialysis session before dialysis immediately after insertion of the catheter into the patient's artery Also, at the end of the same dialysis session, the blood flow rate was reduced to 100 ms / min for 10 seconds, and blood samples were taken before and after dialysis for measurement of urea, creatinine, sodium and potassium, and sent to the laboratory. The above tests are routine The monthly is done in the dialysis department Rabbo importance of maintaining the level of serum sodium, potassium, dialysis patients these tests along with urea and creatinine is measured. 100 * urea pre-dialysis / urea dialysis lateral dialysis = URR To calculate the adequacy of dialysis, we use the second generation of Dagridas formula, which is an acceptable formula of the world. In this formula, the natural logarithm, the duration of each hemodialysis session per hour, the proportion of urea after dialysis to pre-dialysis, the weight of the dialysis and the volume of the ultrasound Filtration is on. KT / V = 1.2 100. Urea pre-dialysis / urea dialysis after previous dialysis = URR KT / V = -Ln (R-0/008 × T) + (4--3 / 5T) × 0 / 55UF / V KT / V = Ln (1-URR) It should be noted that according to the division of tasks, data recording, group assignment and their matching are done by the student. Performing dialysis, blood pressure measurements and sampling by nurse, researcher and researcher. Advice and guidance will be provided at all stages by advisor professors.

Main outcome variables

hemodynamic indicators ,dialysis efficiency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171009036675N2**
Registration date: **2018-03-02, 1396/12/11**
Registration timing: **retrospective**

Last update: **2018-03-02, 1396/12/11**
Update count: **0**

Registration date

2018-03-02, 1396/12/11

Registrant information

Name

Fatemeh Kiani

Name of organization / entity

Faculty member, Zahedan University of Medical Scienses

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5715

Email address

f.kiani@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of effect lowering the dialysate temperature on hemodynamic indicators and dialysis efficiency of the diabetic patients in aliabn abitalb (AS) hospital of zahedan university of medical sciences in 2018

Public title

The effect lowering the dialysate temperature on hemodynamic indicators and dialysis efficiency of the diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should have a history of hemodialysis at least three months before the study Non-use of blood pressure reducing drugs is one of the inclusion criterias Patients should have less than 2 kg of weight gain during dialysis Patients who have experienced less than 90 mm Hg systolic pressure in previous sessions of dialysis and experienced related symptoms are included in the study. Patients should not have severe anemia (8Hb <) Patients should not have simultaneous malignancies Not having thyroid disorders is also one of the the inclusion criterias.

Exclusion criteria:
patient's death Incompatible dialysis with cold solution (in case of very severe chills). Consumption of food and fluids is higher than the amount prescribed during dialysis Unwillingness to continue participating in the study

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences, Dr Hesabi Square

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2017-12-24, 1396/10/03

Ethics committee reference number
IR.ZAUMS.REC.1396.292

Health conditions studied

1

Description of health condition studied
Chronic kidney disease

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Hemodynamic indicators

Timepoint
Before and after the intervention

Method of measurement
By thermometer and manometer

2

Description
Dialysis Efficiency

Timepoint
Before and after the intervention

Method of measurement
Based on the KT/V dialysis quality determination formula, more than 1.2 or less than 1.2

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, 32 hemodialysis patients are selected availably and non-randomly, with inclusion criteria, who are referred to hemodialysis unit of Ali ebn Abitalib hospital in Zahedan. Essential descriptions of how the study is conducted and the purpose of the study is given to patients who are asked to read and sign the written consent form and then with regard to age, gender, occupation, education, and compliance with medical ethics and safety, we complete the demographic information of the patients. Patients undergo hemodialysis in two sessions, once with a cold solution (36 ° C) and the next session with a routine or conventional solution (37 ° C). The hemodialysis variables except for temperature are the same in both cases. The hemoglobin is warmed up to 36.5 to 37.5 ° C (normal range) before the hemodialysis. All patients have one type of dialyser and a dialysis solution (with bicarbonate) will be used. In the beginning, all machines are verified for the correctness of the function. In order to harmonize the conditions in this study, the rate of fluid harvesting for each patient is determined based on the weight difference before the patient's pure weight loss. The ambient temperature (23 ° C) is controlled throughout the study. The concentration of sodium fluid in dialysis is constant in all sessions. Blindness does not apply to this study.The study is conducted in 2018. All patients who undergo dialysis 3 times a week and 3-4 hours each are included in the study. The hemodialysis

fluid flow rate is constant at 500 mm / min with a Fresenius 4008-B apparatus and the same ultrafiltration with the same filtration rate, which is constant for all patients during the study. The fluid withdrawal rate for each patient was calculated before the dialysis weight was calculated with the patient's dry weight and the machine's total weight The accuracy and accuracy of the device, blood pressure, and blood pressure of 8 patients are measured 5 times in a 5-minute sitting period. The systolic and diastolic blood pressure of the patients is measured by a digital doped barometric In the early stages of dialysis, during the first, second and third days of dialysis, and immediately after the end of dialysis, the patient's heart rate is measured at the same time as the blood pressure and the same device. Before and after After each dialysis session, the temperature of the mufflers is measured and recorded. In addition, if the patient complains at least one of the symptoms of hypotension, such as muscle cramps, nausea, vomiting, fatigue and dizziness, his blood pressure will be measured at the same time. The number of times the pressure drop and the changes in pressure and number of actions are necessary. In order to heal, the difference in blood pressure is the difference between the systolic and diastolic blood pressure during dialysis, as well as systolic and diastolic blood pressure, and the onset of dialysis. The mean arterial pressure (MAP) is calculated from the sum of systolic and dihidrostheol divided by 3 times. The patient's time is hypotension, with systolic blood pressure lower than 90 mm Hg. In patients whose baseline blood pressure is 100-90 mm Hg , A 25% drop or a decrease of 20 mm in excess of systolic pressure as hypotension. Dialysis adequacy means that dialysis takes up 70% or more of blood urea over a 4-hour dialysis period, and subsequent administration of dialysis should be based on a higher or at least 70% withdrawal rate. The procedure is that in the final dialysis session before dialysis immediately after insertion of the catheter into the patient's artery Also, at the end of the same dialysis session, the blood flow rate was reduced to 100 ms / min for 10 seconds, and blood samples were taken before and after dialysis for measurement of urea, creatinine, sodium and potassium, and sent to the laboratory. The above tests are routine The monthly is done in the dialysis department Rabbo importance of maintaining the level of serum sodium, potassium, dialysis patients these tests along with urea and creatinine is measured. 100 * urea pre-dialysis / urea dialysis lateral dialysis = URR To calculate the adequacy of dialysis, we use the second generation of Dagridas formula, which is an acceptable formula of the world. In this formula, the natural logarithm, the duration of each hemodialysis session per hour, the proportion of urea after dialysis to pre-dialysis, the weight of the dialysis and the volume of the ultrasound Filtration is on. KT / V = 1.2 100. Urea pre-dialysis / urea dialysis after previous dialysis = URR KT / V = -Ln (R-0/008 × T) + (4--3 / 5T) × 0 / 55UF / V KT / V = Ln (1-URR) It should be noted that according to the division of tasks, data recording, group assignment and their matching are done by the student. Performing dialysis, blood pressure measurements and sampling by nurse, researcher and researcher. Advice and guidance will be provided at all stages by advisor professors.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ebn Abitaleb Zahedan Hospital

Full name of responsible person

Fatemeh Kiani

Street address

Ali ebn abitalib hospital, Salamat blvd, Khalije fars Highway

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

Fkiani2011@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

mohsen taheri

Street address

Deputy of Research and Technology , Medical Sciences Campus , Dr. Hesabi Square, Zahedan, Iran

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5796

Email

taheri@zaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Fatemeh Kiani
Position
Instructor, faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
faculty of nursing and midwifery, Mashahir sq.
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3344 2481
Email
f.kiani@zaums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
fatemeh kiani
Position
Instructor, faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
faculty of nursing and midwifery - Mashahir sq.
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Email
f.kiani@zaums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
fatemeh kiani
Position
Instructor, faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
faculty of nursing and midwifery - Mashahir sq
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3344 2481
Email
f.kiani@zaums.ac.ir

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
Undecided - It is not yet known if there will be 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
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
Only the original outcome data will be available
When the data will become available and for how long
After publishing the article in 2018
To whom data/document is available
all people
Under which criteria data/document could be used
Improve treatment conditions
From where data/document is obtainable
Zahedan University of Medical Sciences
What processes are involved for a request to access data/document
Applying from the university research vice president
Comments