

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The survey of the effect of cool dialysate on hemodynamic condition and adequacy of dialysis in hemodialysis patients in Razi hospital, Rasht, Iran, 2019

Protocol summary

Study aim

The aim of this study was to find an effective relationship between reducing dialysis temperature and hemodynamic status during dialysis and the adequacy of dialysis and providing a basis for easier dialysis process and better outcome for hemodialysis.

Design

This is a pre and post quasi experimental study that will be performed on 99 dialysis patients who will be selected by simple sampling. This study was done with the method of before and after on the same patients and did not have a control group.

Settings and conduct

This research is done in dialysis unit of Razi Hospital in Rasht. Patients are subjected to dialysis in three consecutive sessions at 37 ° C. Blood pressure and pulse are measured and recorded before, during and after each dialysis. At the beginning and end of the third session, the BUN blood sample is taken to calculate the adequacy of dialysis. In the next step, these patients undergo dialysis in three consecutive sessions with a temperature of 35.5 ° C and the values of the variables are measured and recorded in the previous method.

Participants/Inclusion and exclusion criteria

Entry requirements: patients undergoing hemodialysis three times a week, history of hemodialysis at least three months before the study, not having cardiovascular disorders, not having thyroid disorders, and willingness to participate in the study. Exit conditions: severe shivering, severe cardiovascular events such as unstable angina pectoris or heart attacks during dialysis, Severe hypotension and unwillingness to continue cooperation.

Intervention groups

We use dialysis solution at 37 ° C and 35.5 ° C for hemodialysis for patients and compare the hemodynamic stability during dialysis and dialysis adequacy in two temperatures.

Main outcome variables

Measurable consequences include systolic blood pressure, diastolic blood pressure, pulse, and dialysis adequacy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080825001083N9**

Registration date: **2019-05-24, 1398/03/03**

Registration timing: **prospective**

Last update: **2019-05-24, 1398/03/03**

Update count: **0**

Registration date

2019-05-24, 1398/03/03

Registrant information

Name

Majid Pourshaikhian

Name of organization / entity

Guilan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2019-09-06, 1398/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The survey of the effect of cool dialysate on hemodynamic condition and adequacy of dialysis in hemodialysis patients in Razi hospital, Rasht, Iran, 2019

Public title
The survey of the effect of cool dialysate on hemodynamic condition and adequacy of dialysis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Dialysis patients undergoing hemodialysis three times a week History of hemodialysis at least three months before the study The desire to participate in the study
Exclusion criteria:
Cardiovascular Disease Thyroid Disorders

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Guilan university of medical sciences
Street address
Namjo Blv - Shahid Ansari street - Facing the 17 Shahrivar hospital

City
Rasht
Province
Guilan
Postal code
4188794755

Approval date
2019-05-11, 1398/02/21
Ethics committee reference number
IR.GUMS.REC.1398.071

Health conditions studied

1
Description of health condition studied
CKD
ICD-10 code
I13.11
ICD-10 code description
Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease

Primary outcomes

1
Description
Systolic blood pressure changes
Timepoint
Initially, during and after dialysis at each stage of hemodialysis
Method of measurement
Digital manometer

2
Description
Diastolic blood pressure changes
Timepoint
Initially, during and after dialysis at each stage of hemodialysis
Method of measurement
Digital manometer

3
Description
Heart rate changes
Timepoint
Initially, during and after dialysis at each stage of hemodialysis
Method of measurement
Digital manometer

4
Description
Adequacy of dialysis
Timepoint
First and the end of third turn of dialysis at two different

temperatures

Method of measurement

Measuring blood BUN and calculating based on Daugirdas-II formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This study is done with a sample size of 99 dialysis patients from Razi Hospital who will be selected by simple sampling method. These patients will undergo dialysis with the same dialysis solution for the compounds in them, the same dialysis filters will be dialyzed at each dialysis for each patient and at the same time each time. Initially, each patient undergoes hemodialysis in three consecutive sessions with a dialysis solution of 37 ° C which is the usual temperature for dialysis and is currently used for this hemodialysis temperature at this center. Blood pressure and pulse of the patient Before each dialysis, during (2 hours after the start of dialysis) and immediately after each dialysis is monitored and recorded. The patient's blood sample is taken to carry out the BUN test before and after the third dialysis so that its results can be used to measure the adequacy of dialysis. In the next three sessions of dialysis, the patient undergoes hemodialysis with a cold dialysis solution at 35.5 ° C, and as before, blood pressure and pulse rates were recorded before, during and after each dialysis, and in the third dialysis, Before and after dialysis, the patient's blood sample is taken for BUN testing. Diastolic and diastolic blood pressure, and the number of pulses recorded at each turn of dialysis, will be used to calculate the mean of these values as well as the difference in mean values at 35.5 ° C and 37 ° C. To monitor patients during dialysis, hemodynamic monitoring and recording, as well as blood sample collection, will be used by one experienced nurse in the dialysis unit as a collaborator. Blood samples taken at two different temperatures are labeled with their number and temperature. After receiving the test responses, the dialysis adequacy ratio (KT / V) for each temperature is calculated and recorded using the formula for the ratio of time clearances to the volume of urea release (KT / V). To calculate KT / V, a computer software that will calculate it based on the Daugirdas II logarithmic formula will be used. To control systolic blood pressure, diastolic blood pressure and pulse rate, the OMRON digital barometer, the Japan-based manufacturing model M3, which is one of the most prominent brands in Iran, will be used.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi educational & therapeut center

Full name of responsible person

Majd Pourshaikhian

Street address

Razi educational & therapeut center, Sardare jangal Ave,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Abdorrasool Sobhani

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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

Rasht 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

Person responsible for general inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Majid Pourshaikhan

Position

MSc of anesthesia/ Faculty member of group of anesthesia of Guilan University of Medical Sciences and

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Email**Person responsible for updating data****Contact****Name of organization / entity**

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Ph.D.

Other areas of specialty/work

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Web page address**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

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 final outcome of the study can be shared for all dialysis patients and other people who have a job relationship with these patients. The total potential data can be shared for researchers and students of medical and paramedical groups after unidentifiable individuals.

When the data will become available and for how long

Start the access period 3 months after printing the results

To whom data/document is available

Dialysis patients, Researchers and students of medical and paramedical groups, Academic and Private Institutions

Under which criteria data/document could be used

The results of the research do not appear to be applicable to non-medical individuals and private companies. However, if necessary, they can contact the researcher of this research (Dr. Majid Pourshikihian) at 00989113304288 or email :
pourshaikhian_m@yahoo.com.

From where data/document is obtainable

Dr.Majid Pourshaikhian - Nursing and Midwifery Faculty

of Rasht - 00989113304288 - E-mail :

pourshaikhian_m@yahoo.com

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

This research is in the form of student dissertation. Therefore, to receive official information and documentation, please contact the Delegation of the Nursing and Midwifery Faculty of Rasht. To speed up the correspondence process, you can contact the researcher (Dr. Majid Pourshikihian) at (00989113304288) or E-mail :
pourshaikhian_m@yahoo.com

Comments