# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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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+98 13 3360 5768

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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 eductional & theraputic center

**Full name of responsible person**

Majd Pourshaikhian

**Street address**

Razi eductional & theraputic center, Sardare jangal Ave,

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http://www.gums.ac.ir/razi

## 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**

Academic

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## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Rasht University of Medical Sciences

**Full name of responsible person**
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**Position**
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Nursery

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## Person responsible for updating data

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## Person responsible for scientific inquiries

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**Position**
Assistant Professor

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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**
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 Pourshikihan) at (00989113304288) or E-mail : pourshaikhian_m@yahoo.com

**Comments**