Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of cool dialysate with normal dialysate on vital signs, patient comfort and adequacy of dialysis in hemodialysis patients

Protocol summary

Summary

Methods:This study aimed to evaluate the effect of cool dialysis in hemodialysis patients and is done in three steps.The study population consisted of 30 patients with end-stage renal failure in the age range 15 to 80 years,that they are at least three months before to become permanent hemodialysis.In the first phase, patients initially will be hemodialysis for three sessions (one week)with dialysate at 37Cº.Before and after each session of dialysis , oral temperature is measured and will be recorded.Systolic and diastolic blood pressure and pulse rate will be measured at the bigining of dialysis, first, second and third hours during dialysis and immediately after dialysis in each session then will be recorded.Number of hypotension episode with signs such as muscle cramps, nausea and vomiting, and interventions to improve it, such as normal saline administration, Trendelenburg position, using hyper tonic solution, reduction of ultrafiltration and slow down the device will be recorded in the check List.At the end of the third session, the comfort of patients will be measured by Visual comfort criteria . To assess the adequacy of dialysis, blood samples will be collected before and after the third session of hemodialysis.In the second phase of the study, the patients will be hemodialysis by a solution of 36 C º for three sessions (one week).The process is exactly the same as the first stage. The only difference is that in addition to monitoring vital signs if patients have feeling cold or shivering must be register in check list.The third phase is quite similar to the second stage, but dialysate temperature is 35 C º.At the end of the study, the patients are asked what temperature they prefer dialysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090810778N1**

Registration date: **2012-11-18, 1391/08/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-11-18, 1391/08/28

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Department of Medical Science and Technology Research of Hamedan University of Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of cool dialysate with normal dialysate on vital signs, patient comfort and adequacy of dialysis in hemodialysis patients

Public title
The effect of reduction of dialysate temperature in hemodialysis patients
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:patients that are in end stage renal disease and Minimum of three months before participating in the study are hemodialysis;None of the blood pressure-lowering drugs on the morning of dialysis are not used; Absence of cardiac disorders such as MI or having a pacemaker; No risk of severe anemia Hb<8 ; Absence of diabetic neuropathy (due to ortho-static hypotension in these patients) ;No one have cancer; Lack of thyroid disorders (due to temperature changes that may occur.) Exclusion criteria:The use of blood pressure decreasing agents before dialysis;Severe heart disorders such as unstable angina and MI occure during the study;Malignant disease such as cancer occure during the study; thyroid disorders occure during the study; Severe shivering, so that the patient may not be able to continue dialysis;Severe and uncontrollable vomiting.
Age
From **15 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
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
Local Human Subject Review board
Street address
Beginnings of Ayatollah Kashani AV, Shariati junction
City
Hamedan
Postal code
Approval date
2012-08-18, 1391/05/28
Ethics committee reference number
1837/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied
End stage kidney disease
ICD-10 code
N18.5
ICD-10 code description
Chronic uraemia End stage kidney disease:•in allograft failure

Primary outcomes

1

Description
Temperature
Timepoint
Before and after dialysis
Method of measurement
Oral Digital Thermometer

2

Description
Blood pressure and pulse
Timepoint
For the first, second, third hour and the end of dialysis
Method of measurement
With digital sphygmomanometer cuff

3

Description
Patient comfort
Timepoint
At the end of the third session
Method of measurement
VAS chart

4

Description
Hemodialysis adequacy
Timepoint
End of the third session
Method of measurement
Measurement of Urea & Creatinine before and after dialysis, according to a formula Daygr DOS 2

Secondary outcomes

1

Description
Feeling cold and shivering
Timepoint
For first, second and third hour

Method of measurement
Questionnaire

Intervention groups

1

Description
Hemodialysate temperature in the second and third weeks, respectively, will decrease to 36 ºC and 35ºC and all patients (cross-over study) for three sessions by each temperature will be undergoing hemodialysis.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamedan's Besat Treatment and Educational Center
Full name of responsible person
Street address
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology,Hamedan University of Medical Sciences
Full name of responsible person
Ahmad tavilani
Street address
Vice Chancellor for Research and Technology,Hamedan University of Medical Sciences,Shahid fahmideh AV
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and Technology,Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Fatemeh Farghadani
Position
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty