

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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 37C^o.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

Fatemeh Farghadani

Name of organization / entity

Hamedan Uuniversity of Medical Sciences

Country

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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 occur during the study; Malignant disease such as cancer occur during the study; thyroid disorders occur 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

*empty***Intervention groups****1****Description**

Hemodialysate temperature in the second and third weeks, respectively, will decrease to 36 °C and 35°C 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****Person responsible for general inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Farghadani

Position

MA student

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department of Internal Medicine - Surgery, Hamedan University of Medical Sciences

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PHD student

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Position

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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