Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of lowering dialysate temperature on the quality of hemodialysis in patients undergoing hemodialysis in 5t Azar hospital

Protocol summary

Summary

This is a clinical trial study with randomized controlled design. The purpose of this study is to determine the effect of reducing dialysate temperature on the quality of hemodialysis in dialysis patients. Our samples are included the patients undergoing hemodialysis in 5th Azar hospital who have the inclusion criteria during one month before of study. Simple random sampling technique was employed to select 50 patients that divided into 2 groups of 25 persons. In crossover study, patients are assessed during 24 dialysis sessions; the first group received hemodialysis for 12 sessions using cool dialysate (35.5°C) and the second group is on hemodialysis with standard dialysate temperature (37°C). Then the method of treatment is replaced in two groups for the next 12 sessions. Hemodynamic parameters including SBP, DBP and heart rate (HR) are recorded hourly, before, during and after dialysis. Clinical complaints and treatment interventions related to hypotension are noted. Oral temperature is measured before and immediately after dialysis. For all patients, dialysis adequacy is measured 5 times and Petersburg Sleep Quality Index (PSQI) questionnaire is checked for three stages; before the intervention, before moving groups and at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306268140N2**
Registration date: **2013-07-14, 1392/04/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-14, 1392/04/23

Registrant information

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Einollah Mollaei
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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology Golestan University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lowering dialysate temperature on the quality of hemodialysis in patients undergoing hemodialysis in 5t Azar hospital

Public title

Effect of lowering dialysate temperature on the quality of hemodialysis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the samples are included the patients undergoing hemodialysis at 5th Azar hospital having:

hypotension in more than 30 percent of dialysis sessions (more than three sessions), during one month before the study; three times dialysis per week with sodium bicarbonate solution; patients did not receive analgesic, anti- hypertensive and anti-spasm during four hours before of dialysis; no history of chronic infections, heart failure, chronic lung disease, drugs / alcohol abuse or require of treatment for mental disorders, severe anemia, coronary artery disease; age more than 18 years old and more than three month's dialysis treatment.

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Golestan University of Medical Sciences

Street address
Kilometer 2 Gorgan sari -Golestan University of Medical Sciences

City
Gorgan

Postal code

Approval date
2013-03-17, 1391/12/27

Ethics committee reference number
340791122702

Health conditions studied

1

Description of health condition studied
End stage kidney disease

ICD-10 code
N18.5

ICD-10 code description
End stage kidney disease

Primary outcomes

1

Description
dialysis adequacy

Timepoint
5 times

Method of measurement
Laboratory method with URR

2

Description
Sleep Quality

Timepoint
3 times

Method of measurement
Petersburg Sleep Quality Index (PSQI) questionnaire

3

Description
Blood pressure

Timepoint
hourly, before, during and after dialysis

Method of measurement
Blood pressure based on mm Hg, monitoring by Gambro AK96 dialysis machine

4

Description
Temperature

Timepoint
before and immediately after dialysis

Method of measurement
Thermometer

5

Description
Muscle cramps

Timepoint
pre, intra & post dialysis

Method of measurement
checklist

Secondary outcomes

empty

Intervention groups

1

Description
In crossover study, patients are assessed during 24 dialysis sessions; the first group received hemodialysis

for 12 sessions using cool dialysate (35.5°C) and the second group is on hemodialysis with standard dialysate temperature (37°C). Then the method of treatment is replaced in two groups for the next 12 sessions. Each patient gets dialysis once with routine temperature and once with cool dialysate. Patients are assessed during 24 dialysis sessions; the first group receives hemodialysis for 12 sessions using cool dialysate (35.5°C) and the second group is on hemodialysis with standard dialysate temperature (37°C). Then the method of treatment is replaced in two groups for the next 12 sessions. During the study, all the dialysis conditions are maintained the same except temperature of dialysate (37°C or 35.5°). All patients are on hemodialysis using GAMRO AK96 hemodialysis machine.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis therapy 5t Azar hospital
Full name of responsible person
Street address
City
Gorgan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Golestan University of Medical Sciences
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Golalipour Mohammad Jafar
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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
Golestan 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
Golestan University of Medical Sciences
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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