Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of cold dialysate on the prevalence of cardiac arrhythmias and hemodynamic status during dialysis

Protocol summary

Study aim
Comparison of prevalence of cardiac arrhythmias during dialysis in dialysis group with standard temperature of 37 ° C and dialysis group with temperature of 36 ° C. Comparison of hemodynamic status in dialysis group with standard temperature of 37 °C and dialysis group with temperature of 36 °C

Design
This study is a single-blind crossover clinical trial in patients undergoing hemodialysis. A total of 35 patients were selected using the available method. Each sample participated in the study twice.

Settings and conduct
Each sample participated in the study twice. Patients were dialysed for one month with dialysate temperature at 37 ° C and one month (second time) with dialysate temperature at 36 ° C. The observer is blind to the type of intervention.

Participants/Inclusion and exclusion criteria
-The patient must be at least 18 years of age - Patients have undergone hemodialysis at least 3–6 months prior to the study -Patients have not received antiarrhythmic drugs (inotropic, Digoxin, Beta blockers, etc.(. - The patient's blood pressure should not exceed 150/100 mmHg. -The patient death -Lack of desire to continue to participate in the study - Intolerance to cold dialysate (in case of severe chills) - If the patient's blood pressure rises, 30mmHg higher than the initial blood pressure or becomes more than 170mmHg

Intervention groups
Dialysate temperature with 36 ° C in intervention group Dialysate temperature with 37 ° C in control group

Main outcome variables
The prevalence of cardiac arrhythmias ; hemodynamic status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131228015965N16**
Registration date: **2020-02-06, 1398/11/17**
Registration timing: **retrospective**

Last update: **2020-02-06, 1398/11/17**
Update count: **0**

Registration date
2020-02-06, 1398/11/17

Registrant information

Name
Majid Kazemi

Name of organization / entity
Rafsanjan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-19, 1397/11/30

Expected recruitment end date
2019-09-21, 1398/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of cold dialysate on the prevalence of cardiac arrhythmias and hemodynamic status during dialysis

Public title
The effect of cold dialysate on the prevalence of cardiac arrhythmias and hemodynamic status during dialysis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients have been under hemodialysis for at least 6- 3 months prior to the study Patients have not received antiarrhythmic drugs (inotropic, digoxin, beta blockers, etc.). The patient's blood pressure should not exceed 150/100 mmHg
Exclusion criteria:
Patient death Unwillingness to continue participating in the study Intolerance to cold dialysis solution (if it is severe chills) In the event of an increase in blood pressure, the patient will have 30mmHg more than the baseline or greater than 170mmHg
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Reviews of arrhythmias are blind to the intervention.
Placebo
Not used
Assignment
Crossover
Other design features
In this study, patients were studied in two hemodialysis courses. The first period of one month is hemodialysis with dialysate at a standard temperature of 37 ° C. The second period is dialysed with a dialysate (36 ° C) for one month.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Rafsanjan University of Medical Sciences
Street address
Imam Ali Blvd.
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Rafsanjan
Province
Kerman
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7717676563
Approval date
2018-12-22, 1397/10/01
Ethics committee reference number
IR.RUMS.REC.1397.164

Health conditions studied

1

Description of health condition studied
Chronic renal failure
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Percentage of arrhythmias during hemodialysis
Timepoint
Since the beginning of hemodialysis to an hour after dialysis
Method of measurement
Central Monitor,Holter monitoring

2

Description
hemodynamic status (Blood pressure, heart rate, respiratory rate, temperature)
Timepoint
Since the beginning of hemodialysis to an hour after dialysis
Method of measurement
Central Monitor

Secondary outcomes

1

Description
Stability of cardiovascular status during dialysis
Timepoint
Since the beginning of hemodialysis to an hour after dialysis
Method of measurement
central monitor، Holter monitoring

Intervention groups

1

Description
Intervention group: Dialysate is a pharmed pharmacy company that contains sodium, potassium, magnesium, calcium and bicarbonate ions at temperatures of 36 ° C.
Category
Treatment - Drugs

2

Description
Control group: Dialysate is a pharmed pharmacy company that contains sodium, potassium, magnesium, calcium and bicarbonate ions at temperatures of 37 ° C.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alibn Abi Talb hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Rafsanjan 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

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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