

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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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Iran (Islamic Republic of)

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dr.kazemi.n@rums.ac.ir

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.

City

Rafsanjan

Province

Kerman

Postal code

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

Dr.Majid Kazemi

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Sponsors / Funding sources

1

Sponsor

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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

Rafsanjan University of Medical Sciences

Full name of responsible person

Forozande Vatanparast

Position

student

Latest degree

Master

Other areas of specialty/work

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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