

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3425 7663

##### Email address

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

#### Street address

Emam Ali Blvd

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#### Email

Maj\_kaz@yahoo.com

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<https://rums.ac.ir>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Rafsanjan University of Medical Sciences

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Dr.Majid Kazemi

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Dr.kazemi.n@rums.ac.ir

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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

Nursery

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Rafsanjan University of Medical Sciences

#### Full name of responsible person

Dr.Majid kazemi

#### Position

Associate Professor

#### Latest degree

Ph.D.  
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## Person responsible for updating data

### Contact

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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