

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of different potassium and bicarbonate levels of hemodialysis solutions on QTc interval of patients under chronic hemodialysis

#### Protocol summary

##### Summary

1)objectives:The effect of different potassium and bicarbonate levels of hemodialysis solutions on QTc interval of patients under chronic hemodialysis.  
2)Design:Single blind randomized controlled trial.  
3)Setting and conduct:35 patients older than 18 years with a history of hemodialysis for more than 6 months were selected.Each patient will be on dialysis for 4 hours with one of the following solutions: Solution 1: K = 2, HCO<sub>3</sub> = 24, Na = 140, Ca = 1.25 Solution 2: K = 2, HCO<sub>3</sub> = 28, Na = 140, Ca = 1.25 Solution 3: K = 3, HCO<sub>3</sub> = 24, Na = 140, Ca = 1.25 Solution 4: K = 3, HCO<sub>3</sub> = 28, Na = 140, Ca = 1.25 Before and one hour after hemodialysis ECG will be taken and a cardiologist who is unaware of dialysate will measure QTc and changes will be registered.Venous gas and electrolyte concentrations before initiation of dialysis will be registered.  
4)Participants:chronic kidney disease requiring chronic hemodialysis. Inclusion criteria:All chronic kidney disease requiring chronic hemodialysis. Exclusion criteria:Any arrhythmia; Ejection Fraction under 40%; Use of anti arrhythmic drugs other than beta-blockers; The occurrence of hypotension during dialysis; Previous coronary heart disease. 5)Interventions:change of potassium and bicarbonate levels of hemodialysis solutions. 6)main outcome measures:QTc interval changes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013021011194N3**  
Registration date: **2014-09-23, 1393/07/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-09-23, 1393/07/01

##### Registrant information

###### Name

Foroogh Sabzghabaei

###### Name of organization / entity

Tehran University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8214 1600

###### Email address

f-sabzghabaei@tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research,Iran uneversity of medical science 5th floor, iran university of medical science, junction of sheikh fazlollah & chamran highway, hemmat highway tehran

##### Expected recruitment start date

2014-08-01, 1393/05/10

##### Expected recruitment end date

2014-10-01, 1393/07/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of different potassium and bicarbonate levels of hemodialysis solutions on QTc interval of patients under chronic hemodialysis

##### Public title

The effect of different potassium and bicarbonate levels of hemodialysis solutions on QTc interval of patients

under chronic hemodialysis

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria:All chronic kidney disease requiring chronic hemodialysis. Exclusion criteria:Any arrhythmia; Ejection Fraction under 40%; Use of anti arrhythmic drugs other than beta-blockers; The occurrence of hypotension during dialysis; Previous coronary heart disease.

#### **Age**

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

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **35**

#### **Randomization (investigator's opinion)**

Not randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Crossover

#### **Other design features**

## **Secondary Ids**

### **1**

#### **Registry name**

no

#### **Secondary trial Id**

no

#### **Registration date**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethic committee of Iran university of medical science

##### **Street address**

5th floor, Iran university of medical science, junction of Sheikh Fazlollah & Chamran highway,Hemmat Highway

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2014-07-28, 1393/05/06

#### **Ethics committee reference number**

105/2128/93/3

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

End stage kidney disease

#### **ICD-10 code**

N18.5

#### **ICD-10 code description**

Chronic kidney disease, stage 5

## **Primary outcomes**

### **1**

#### **Description**

QT interval

#### **Timepoint**

Before and after dialysis

#### **Method of measurement**

bazzet formula

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

changing potassium and bicarbonate levels of hemodialysis solutions in intervention group -No control group

#### **Category**

Treatment - Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Firoozgar Hospital

##### **Full name of responsible person**

Dr. Foroogh Sabzghabaei

##### **Street address**

Behafarin St., Karimkhan Zand Ave., Valiasr Sq

##### **City**

Tehran

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research,Iran uneversity of medical science

##### **Full name of responsible person**

dr.Morteza Naserbakht

**Street address**

5th floor, Iran university of medical science, junction of Sheikh Fazlollah & Chamran highway, Hemmat highway

**City**

Tehran

**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, Iran university of medical science

**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**

Iran University of Medical Science

**Full name of responsible person**

Dr. Foroogh Sabzghabaei

**Position**

Nephrologist/ assistant professor

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**Web page address****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*