Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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, HCO3 = 24, Na = 140, Ca = 1.25 Solution 2: K = 2, HCO3 = 28, Na = 140, Ca = 1.25 Solution 3: K = 3, HCO3 = 24, Na = 140, Ca = 1.25 Solution 4: K = 3, HCO3 = 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
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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 commitee 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/د

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

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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

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5th floor, Iran university of medical science, junction of Sheikh Fazlollah & Chamran highway, Hemmat highway
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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
Vice chancellor for research,Iran uneversity 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
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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