Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Clinical trials of effect of fluid therapy with half saline compared to normal saline on Creatinine level in post-renal transplant patients

Protocol summary

Summary

Objectives: The current study will aim to compare the effect of fluid therapy with normal saline and half saline on Creatinine level in patients after renal transplant. Design: This is a triple-blind, randomized clinical trial. Setting and conduct: One hundred patients using random block method were randomly assigned into two groups. In one group half saline serum plus 250 milliequivalents Sodium Bicarbonate and in the second group, normal saline serum plus 50 milliequivalents Sodium Bicarbonate will be infused. This clinical trial is a phase 3 study. This is a triple-blind randomized clinical trial. In this study, the patients, those who measure the outcomes of study (researchers) and Data Monitoring Committee (analyzers) will be unaware about intervention. Inclusion criteria: Age between 18 to 65 years; Exclusion criteria: The patient's potassium is higher than 5.5; Patients with chronic heart failure Ejection Fraction less than 30%; Patients with liver failure; The patient needs to have colloidal fluid and blood intake; Severe acidosis; Main outcome measures (variables): The level of creatinine, urine volume, blood pressure, heart rate, blood BUN, etc. will be recorded on the first, second, third and seventh days after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080535510N1**
Registration date: **2017-09-13, 1396/06/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-13, 1396/06/22

Registrant information

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Pejman Pourfakhr
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trials of effect of fluid therapy with half saline compared to normal saline on Creatinine level in post-renal transplant patients

Public title

Effect of fluid therapy on Creatinine level in post-renal transplant patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 to 65 years; Exclusion criteria: The patient's potassium is higher than 5.5; Patients with chronic heart failure Ejection Fraction less

than 30%; Patients with liver failure; The patient needs to have colloidal fluid and blood intake; Severe acidosis;

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Keshvarz Blvd

City
Tehran

Postal code

Approval date
2016-12-26, 1395/10/06

Ethics committee reference number
IR.TUMS.VCR.REC.1395.1565

Health conditions studied

1

Description of health condition studied
Chronic kidney disease

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease

Primary outcomes

1

Description
Creatinine

Timepoint
In the first, second, third and seventh days after the intervention

Method of measurement
Blood test

2

Description
Urine volume

Timepoint
In the first, second, third and seventh days after the intervention

Method of measurement
Urine test

Secondary outcomes

1

Description
Systolic blood pressure

Timepoint
In the first, second, third and seventh days after the intervention

Method of measurement
Invasive blood pressure monitor

2

Description
Systolic blood pressure

Timepoint
In the first, second, third and seventh days after the intervention

Method of measurement
Invasive blood pressure monitor

3

Description
Heart rate per minute

Timepoint
In the first, second, third and seventh days after the intervention

Method of measurement
Invasive blood pressure monitor

Intervention groups

1

Description
Control group: Serum normal saline plus 50 mili-Equivalents Sodium Bicarbonate will be infused.

Category
Prevention

2

Description
Intervention group: Serum half Saline plus 250 mili-Equivalents Sodium Bicarbonate will be infused.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital of Tehran University of Medical Sciences
Full name of responsible person
Mohadeseh Shafiee
Street address
Hassan Abad square, Emam Khomeini Street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Masoud Yunesian
Street address
Tehran University of Medical Sciences, Keshavarz Blvd
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, Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
Full name of responsible person
Mohadeseh Shafiee
Position
Student/Anesthesiology resident
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Person responsible for scientific inquiries

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Person responsible for updating data

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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