

# 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

##### Name

Pejman Pourfakhr

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4466 3963

##### Email address

pourfakhr@tums.ac.ir

#### 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 milli-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

#### Other areas of specialty/work

#### Street address

Tehran University of Medical Sciences, Keshavarz Blvd

#### City

Tehran

#### Postal code

#### Phone

+98 21 4466 3963

#### Fax

#### Email

mds.shafiei@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Pejmal Pourfakhr

#### Position

Faculty member/Anesthesiologist

#### Other areas of specialty/work

#### Street address

Tehran University of Medical Sciences, Keshavarz Blvd

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pourfakhr@tums.ac.ir

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohadeseh Shafiee

#### Position

Student/Anesthesiology resident

#### Other areas of specialty/work

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#### Fax

#### Email

mds.shafiei@gmail.com

**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*