

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Effect of hypertonic saline 5% and sodium bicarbonate 8.4% on early graft function and the urinary levels of IL-18 and Neutrophil Gelatinase-associated Lipocalin (NGAL) as biomarkers of acute kidney injury in patients receiving kidney transplants from deceased donors

#### Protocol summary

##### Summary

The study designed to evaluate the effect of the intra-operative administration of hypertonic saline 5 % and sodium bicarbonate 8.4% on early graft function and urinary levels of Neutrophil Gelatinase Associated Lipocalin (NGAL) and Interleukin-10 (IL-10). The patients age of 18 to 65 years old who receive kidney transplant from decease donor were included in this study and any patient with sever acidosis and/or electrolytes abnormality were excluded. A total of 60 patients were randomly assigned to three groups: hypertonic saline, sodium bicarbonate and control; In the control group, patients receive 60 ml/kg of normal saline as intraoperative fluid therapy. In hypertonic saline, 4 ml/kg hypertonic saline 5% administered about 30 minutes before the declamping of kidney artery. In Sodium bicarbonate group, intraoperative pH is controlled tightly based on Base deficit values by administration of sodium bicarbonate 8.4% and base deficit maintain above -5 mmol/L. The primary outcomes are early graft function and urinary levels of IL- 18 and NGAL. To asses early graft function, serum creatinin, BUN and urine volume is measured in predefine time ponits.

#### General information

##### Acronym

NGAL: neutrophil Gelatinase-associated Lipocalin.  
IL-10;interleukin 10 DGF:delay graft func

##### IRCT registration information

IRCT registration number: **IRCT2013122815841N1**  
Registration date: **2014-01-16, 1392/10/26**  
Registratation timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-01-16, 1392/10/26

##### Registrant information

###### Name

Gholamreza Pourmand

###### Name of organization / entity

Urology Research Center, Tehran University of Medical Sciences, Tehran, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6634 8560

###### Email address

pourmand@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

TUMS

##### Expected recruitment start date

2013-09-23, 1392/07/01

##### Expected recruitment end date

2014-08-22, 1393/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of hypertonic saline 5% and sodium bicarbonate 8.4% on early graft function and the urinary levels of IL-18 and Neutrophil Gelatinase-associated Lipocalin (NGAL) as biomarkers of acute kidney injury in patients receiving kidney transplants from deceased donors

**Public title**

comparison the effect of hypertonic saline and sodium bicarbonate on early graft function in kidney transplantation

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria:patients candidate for a kidney transplant from deceased donor;the ages of 18 to 65;left ventricular ejection fraction >30%. Exclusion criteria:sever acidosis (pH<7.2 and/or HCO<sub>3</sub><15 and/or BD<-15);serum K>5.5 or serum K<3.5;serum Na>150 or serum Na<135;blood product transfusion

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

TUMS-Ethics committee in research

**Street address**

keshavars st

**City**

tehran

**Postal code****Approval date**

2013-12-28, 1392/10/07

**Ethics committee reference number**

92-02-47-23360-102797

**Health conditions studied****1****Description of health condition studied**

kidney transplantation

**ICD-10 code**

Z94.0

**ICD-10 code description**

Kidney transplant status

**Primary outcomes****1****Description**

serum creatinin

**Timepoint**

befor,0,6,12,24hr after operation and 2,3 and 7 days after transplant

**Method of measurement**

jaffe method

**2****Description**

BUN

**Timepoint**

befor,0,6,12,24hr after operation and 2,3 and 7 days after transplant

**Method of measurement**

colorimetric method

**3****Description**

urin volume

**Timepoint**

recovery, 6, 12, 24, 48 hr after operation

**Method of measurement**

obsevation

**4****Description**

NGAL

**Timepoint**

0,24,48 hr after operation

**Method of measurement**

ELISA

**5****Description**

IL-10

**Timepoint**

0,24,48 hr after operation

**Method of measurement**

ELISA

**Secondary outcomes****1****Description**

base deficit

**Timepoint**

before and every 30 minutes during operation

**Method of measurement**

ABG analyzer

**2**

**Description**

serum K

**Timepoint**

before and during operation

**Method of measurement**

flame photometry

**3**

**Description**

HCO<sub>3</sub>

**Timepoint**

before and every 30 minutes during operation

**Method of measurement**

ABG analyzer

**4**

**Description**

pCO<sub>2</sub>

**Timepoint**

before and every 30 minutes during operation

**Method of measurement**

ABG analyzer

**5**

**Description**

serum Cl

**Timepoint**

before and during operation

**Method of measurement**

flame photometry

**6**

**Description**

serum Na

**Timepoint**

before and during operation

**Method of measurement**

flame photometry

**7**

**Description**

pO<sub>2</sub>

**Timepoint**

before and every 30 minutes during operation during operation

**Method of measurement**

mmHg-ABG analyzer

**8**

**Description**

pH

**Timepoint**

before and every 30 minutes during operation

**Method of measurement**

ABG analyzer

**Intervention groups**

**1**

**Description**

hypertonic saline group: 4ml/kg hypertonic saline 5% is administered before declamping during kidney transplant procedure.

**Category**

Treatment - Drugs

**2**

**Description**

control group; 60 ml/kg normal saline solution administered during kidney transplant procedure to maintain CVP between 8 and 15 cm H<sub>2</sub>O

**Category**

Treatment - Drugs

**3**

**Description**

sodium bicarbonate group: during kidney transplant procedure pH is controlled tightly based on BD values by administration of sodium bicarbonate 8.4% and BE maintained above -5 m mol/L.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Sina Hospital

**Full name of responsible person**

Javad Motaharinia-clinical pharmacy resident

**Street address**

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Research Council of Tehran University of Medical Sciences

**Full name of responsible person**

Research Council of Tehran University of Medical Sciences

**Street address**

Research Council of Tehran University of Medical Sciences-Qods building-boulvar keshavarz

**City**

Qods building-boulvar keshavarz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Council of 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**

Farhad Etezadi

**Position**

anesthesiologist,assistant professor

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## Person responsible for updating data

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**Other areas of specialty/work**

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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*