

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

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Name of organization / entity

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

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+98 21 6634 8560

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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 HCO3<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

HCO₃

Timepoint

before and every 30 minutes during operation

Method of measurement

ABG analyzer

4

Description

pCO₂

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

pO₂

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 H₂O

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

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