

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of effects of rapid infusion of normal saline during vessel anastomosis on graft function and acid base balance in kidney transplantation surgery

#### Protocol summary

##### Summary

Introduction: Infusion of large volumes of normal saline (N/S) was recommended for facilitating graft function in kidney transplantation surgery but it can cause severe metabolic acidosis. This study is going to evaluate effects of rapid infusion of N/S during vessel anastomosis period on acid base, electrolytes and graft function. Methods and materials: In a self-control clinical trial 30 candidates for reception of kidney from live donors are evaluating during kidney transplantation. Inclusion criteria are age 18 to 65 y/o, no previous kidney transplantation, ejection fraction more than 45% and exclusion criteria are bleeding more than 3cc/kg and vessel anomaly in donors kidney. During vessel anastomosis period Infusion of N/S is increasing from 10 ml/kg/h to 50 ml/kg/h and acid base balance, electrolytes and anion gap are measuring and comparing at the beginning and end of surgery. Serum creatinine and urine output till 48 hours after surgery are going to measure and analyze too.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014041516415N1**

Registration date: **2014-04-15, 1393/01/26**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-04-15, 1393/01/26

##### Registrant information

###### Name

Mohammad Golparvar

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3220 1750

###### Email address

golparvar@med.mui.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Department of kidney transplantation of St Alzahra Hospital

###### Expected recruitment start date

2014-03-01, 1392/12/10

###### Expected recruitment end date

2014-09-30, 1393/07/08

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Evaluation of effects of rapid infusion of normal saline during vessel anastomosis on graft function and acid base balance in kidney transplantation surgery

###### Public title

Evaluation of effects of rapid infusion of normal saline during vessel anastomosis on graft function and acid base balance in kidney transplantation surgery

###### Purpose

Diagnostic

###### Inclusion/Exclusion criteria

Inclusion criteria: age between 18-65 years old; end stage renal disease; candidate of elective live donor kidney transplantation; no previous kidney

transplantation; no liver disease; ejection fraction more than 45%; ASA I and II Exclusion criteria: Bleeding more than 3 ml/kg; vascular anomaly in donor kidney

#### 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: **30**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

This is a self control study (condition of cases before intervention are using as control cases)

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan university of medical sciences

##### Street address

Isfahan, University boulevard, Isfahan university of medical sciences

##### City

Isfahan

##### Postal code

#### Approval date

2012-07-11, 1391/04/21

#### Ethics committee reference number

391192

## Health conditions studied

### 1

#### Description of health condition studied

Chronic kidney disease, stage 5

#### ICD-10 code

N18.5

#### ICD-10 code description

Chronic uraemia End stage kidney disease: in allograft failure NOS on dialysis without dialysis or transplant

## Primary outcomes

### 1

#### Description

Anion Gap

#### Timepoint

Before and after fluid infusion

#### Method of measurement

Calculation of anion gap by measuring blood gas analysis and and blood electrolytes concentration

## Secondary outcomes

### 1

#### Description

Electrolyte concentration, urine output, blood creatinine concentration

#### Timepoint

Before and after fluid infusion, 24 and 48 hours after surgery

#### Method of measurement

Blood sampling and urine collection

## Intervention groups

### 1

#### Description

Intervention: Rapid infusion of normal saline during vessel anastomosis Control: none

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

St Alzahra Hospital

##### Full name of responsible person

Hashemi Mozaffar MD

##### Street address

Department of Kidney Transplantation, St Alzahra Hospital, Sofeh boulevard, Isfahan, Iran

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Department of Transplantation of St Alzahra Hospital

##### Full name of responsible person

Amini Marzieh Mrs

##### Street address

St-Alzahra Hospital, Sofeh Boulevard, Isfahan, Iran

**City**  
Isfahan

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**  
Department of Transplantation of St Alzahra Hospital

**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**  
St Alzahra Hospital

**Full name of responsible person**  
Hashemi Mozaffar MD

**Position**  
Associated professor in Medical School of Isfahan  
University of Medical Sciences

**Other areas of specialty/work**

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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*