

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)

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Email address

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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
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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