

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The effect of Ascorbic Acid infusion during renal transplantation on post-operative renal function status in the Kidney Transplantation Patients

Protocol summary

Summary

Objective: To investigate the effect of administration of vitamin C during kidney transplantation surgery on postoperative renal function. Study design: Triple blind randomized clinical trial. Inclusion criteria: patients who are undergoing kidney transplantation. Exclusion criteria: drug sensitivity; cardiomyopathy; chronic obstructive pulmonary disease (COPD) and respiratory diseases; intraoperative hypotension; inotrope requirement during the surgery. Intervention: The 64 kidney recipients were divided into two groups (A & B). The patients in group "A" received infusion of 100 mg / kg (total volume with normal saline 50 cc) within 6 hours, and patients in group "B" received infusion of normal saline(50 cc) within 6 hours. Venous blood sampling was done for all patients in 3 stages (at the beginning of the operation, 1 and 2 hours after declamping of renal artery) to check MDA (Malondealdehyde) and TAC (total antioxidant status) as markers of free oxygen radicals activity and body oxidant status. Also graft function was monitored by measurement of BUN, creatinine, GFR and need for hemodialysis on the first 5 days and also 1 month after transplantation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081319470N37**

Registration date: **2016-09-04, 1395/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-04, 1395/06/14

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Science

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ascorbic Acid infusion during renal transplantation on post-operative renal function status in the Kidney Transplantation Patients

Public title

The effect of Ascorbic Acid infusion during kidney transplantation on post-operative renal function in the Kidney Transplantation Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients who are undergoing kidney transplantation. Exclusion criteria: drug sensitivity; cardiomyopathy; chronic obstructive pulmonary disease

(COPD) and respiratory diseases; intraoperative hypotension; inotrope requirement during the surgery.

Age

To 60 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

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

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

In order to randomization, by using the site www.randomization.com twenty-frequency (permutation) binary of A and B were made then draw the group receiving vitamin C (A or B) is determined. To assign patients to one of the two groups two patients who are supposed to use a donor kidneys become a pair. Of the individual pairs that his/her last name comes first in alphabetical view is selected as the upper part of the B-A block. if the alphabetical view of the initial word of the family name was similar then we will use the alphabetical order of the first name and if similar initial word of the father name and at least national code will be used. After obtaining consent patients without the knowledge that which of the syringe is vitamin C or saline divided into two groups of case and control. (Syringes with volume of 50 cc and same shape. And a person who is unaware of the study prepares Syringes with labeled A, B on which they put at the disposal of researchers.)

Secondary Ids

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of Research, Shiaz University of Medical Sciences, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code**Approval date**

2016-03-05, 1394/12/15

Ethics committee reference number

IR.SUMS.MED.1394.S87

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

Kidney transplant

ICD-10 code

Z94.0

ICD-10 code description

Kidney transplant status

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

to check the MDA (Malondialdehyde)

Timepoint

In 3 stages (at the beginning of the operation, 1 and 2 hours after declamping of renal artery)

Method of measurement

by spectrophotometry

2**Description**

to check the TAC (total antioxidant status)

Timepoint

In 3 stages (at the beginning of the operation, 1 and 2 hours after declamping of renal artery)

Method of measurement

spectrophotometry

3**Description**

graft function of kidney monitoring after transplantation

Timepoint

daily for 5 days in the ICU and one month after kidney transplantation

Method of measurement

measurement of BUN, creatinine, GFR and need for hemodialysis

Secondary outcomes

empty

Intervention groups**1****Description**

patients in group A received vitamin C 100 mg / kg (total volume with normal saline 50 cc) within 6 hours

Category

Treatment - Drugs

2

Description

Patients in the control group received a 50 cc normal saline within 6 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Dr Mohammad Bagher Khosravi

Street address

Namazi Hospital, Namazi squer

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiaz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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Vice Chancellor of Research, 7th Floor of Central Building of Shiraz University of Medical Sciences, Zand streetl

City

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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, Shiaz 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

Shiraz University of Medical Sciences

Full name of responsible person

Seeyed Javad Enjoo

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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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Name of organization / entity

Shiraz Anesthesiology and Critical Care Research Center

Full name of responsible person

Farzaneh Masihi

Position

English Consultant

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