

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Early Outcome of Kidney Function After Transplantation when Use Vitamin C in Deceased Donors.

Protocol summary

Summary

After getting permission from the ethics committee of Shiraz University of Medical Sciences and consultation with Statistics, 30 patients are identified by the group of brain death for organ donation in Nemazee Hospital, randomly divided into two groups based on computer randomize. In Group 1, in ICU of brain death, 100 mg / kg ascorbic acid is infused over 20 minutes and continues with 100 mg / kg for 6 hours before organ harvesting. In group 2, the same volume of Normal-Saline is infused as a placebo to the patient. To check the status of renal ischemia, baseline values of NGAL is measured in all brain death patients in ICU prior to starting ascorbic acid and then repeat, before aortic clamping in donors and 4 hours after renal artery declamping in recipients. After 24 hours, the amount of NGAL is measured in ward and then renal function is evaluated by the amount of BUN, Cr and urine output. Also the total of diuretic drugs and frequency of dialysis will study for 5 days post operation period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070411853N2**

Registration date: **2013-09-08, 1392/06/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-08, 1392/06/17

Registrant information

Name

Mohammad Firoozifar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 7636

Email address

firoozifar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Transplant Research Center, Shiraz University of Medical Sciences Anesthesiology and Critical Care Research Center, Shiraz University of Medical Sciences

Expected recruitment start date

2013-07-06, 1392/04/15

Expected recruitment end date

2014-01-05, 1392/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Early Outcome of Kidney Function After Transplantation when Use Vitamin C in Deceased Donors.

Public title

Effect of Vitamin C in Kidney Function After Transplantation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Brain Death Patients in range of 20-65 years old ; Patients with History of kidney problems under Dialysis in list of Transplantation; Patients with kidney problems with Age between 20-60 years
Exclusion criteria: Brain Death Patients with history of cardiac problems; Brain Death Patients with Cr>1.5

mg/dl; Brain Death Patients with Age>65 year; Patients with kidney problems with Age>65 years old

Age

To 65 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 180

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Zand Street

City

Shiraz

Postal code

Approval date

2013-04-25, 1392/02/05

Ethics committee reference number

CT-P-92-5005

Health conditions studied

1

Description of health condition studied

kidney transplantation

ICD-10 code

N17.0

ICD-10 code description

Acute renal failure with tubular necrosis

Primary outcomes

1

Description

NGAL (Neutrophil gelatinase- associated lipocalin)

Timepoint

baseline values of NGAL is measured in all brain death patients in ICU prior to starting ascorbic acid and then repeat, before aortic clamping in donors and 4 and 24 hours after renal artery declamping in recipients.

Method of measurement

By Keith

2

Description

BUN

Timepoint

for 5 days post operation

Method of measurement

Lab

3

Description

Cr

Timepoint

for 5 days post operation

Method of measurement

Lab

4

Description

frequency of dialysis

Timepoint

for 5 days post operation

Method of measurement

measured in ward

5

Description

Total diuretic drugs

Timepoint

for 5 days post operation

Method of measurement

measured in ward

Secondary outcomes

empty

Intervention groups

1

Description

In this study, we investigated the protective effects of Ascorbic acid(1000 mg I.V. in intervention group) in renal cell damage due to ischemic-re perfusion injury, by measuring NGAL level in brain death patients in ICU, and follow function of these kidneys after transplant in operating room and in ward by repeated measuring of this bio marker

Category

Prevention

2

Description

In control group 10cc N/S (Equivalent with 2 Ampul of Vitamin C) is injected within 6 hours.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Firoozifar

Street address

Nemazi Hospital ,Zand Street, Shiraz, Fars, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Hatam, Vice-Chancellery of Research and Technology

Street address

Zand street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Mohammad Bagher Khosravi

Position

Associate Professor of Department of Anesthesiology

Other areas of specialty/work

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Full name of responsible person

Mohammad Firoozifar

Position

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Web page address

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