Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Evaluation of the effect of pretransplant, high-dose intravenous vitamin C in prevention of delayed graft function after deceased kidney transplantation

Protocol summary

Study aim
Clinical evaluation of Delayed graft function (DGF) after kidney transplantation between the vitamin C arm and the placebo

Design
A double-blind, randomized clinical trial with a control group and a placebo group design of 50 patients

Settings and conduct
- This study will be conducted in a double blinded clinical trial with placebo in the kidney transplantation section of Imam Khomeini Hospital. - The study will begin after the receipt of the code of ethics and receive the approval of the Ethics Committee. - Patients undergoing kidney transplants for the first time will be considered for inclusion in the study and admission criteria. - In case of informed consent, patients will be introduced. - Patients are divided into two arms of treatment with vitamin C and placebo base on Permuted Block Randomization .

Participants/Inclusion and exclusion criteria
Inclusion criteria: The first kidney transplantation Deceased donor Recipient age 14 years and older Patient informed consent to enter the study Non-inclusion criteria: Hemochromatosis Documented hyperoxaluria Multi organ transplantation History of Fauvism Preemptive kidney transplantation Exclusion Criteria: Patient's dissatisfaction with the continuation of research after entering the study

Intervention groups
- Patients in the treatment arm receive 70 mg/kg vitamin C (at least 3 grams) at last hour before transplant surgery. The calculated dose is diluted in 250 ml of sodium chloride solution (0.45%) and infused over an hour before the transplant. In the placebo group, placebo (a saline solution of similar volume) is prescribed at that time.

Main outcome variables
dialysis in the first week after transplantation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100111003043N13**
Registration date: **2019-06-24, 1398/04/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-24, 1398/04/03**
Update count: **0**

Registration date
2019-06-24, 1398/04/03

Registrant information

Name
Simin Dashti-Khavidaki

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 6695 4709

Email address
dashtis@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-20, 1398/03/30

Expected recruitment end date
2019-12-20, 1398/09/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of pretransplant, high-dose intravenous vitamin C in prevention of delayed graft function after deceased kidney transplantation

Public title
Evaluation of the effect of pretransplant, high-dose intravenous vitamin C in prevention of delayed graft function after deceased kidney transplantation

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
First kidney transplantation Brain death donor Transplant recipient age 14 or more Patient informed consent to enter the study

Exclusion criteria:
Hemochromatosis ESRD due to hyperoxaluria Multi-organ transplantation Favism history Preemptive kidney transplantation

Age
From **14 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
This is a randomized, double-blind randomized, placebo-controlled clinical trial. The conditions are subdivided by using Permuted Block Randomization method into foursquare blocks randomly in two groups receiving injected intravenous vitamin C or placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
The placebo group, which is serum half-saline alone, receives the same volume in comparison to the drug. Since the drug does not have color, half-saline serum is used with the same volume as placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of The Institute of Pharmaceutical Sciences -Tehran University of Medical

Street address
Tehran University of Medical Sciences, 16 Azar ave., Tehran

City
Tehran

Province
Tehran

Postal code
14155-6451

Approval date
2019-04-16, 1398/01/27

Ethics committee reference number
IR.TUMS.TIPS.REC.1398.007

Health conditions studied

1

Description of health condition studied
Complications of kidney transplant

ICD-10 code
T86.1

ICD-10 code description
Complications of kidney transplant

Primary outcomes

1

Description
Dialysis in the first week after the kidney transplant

Timepoint
Daily in the first week after the kidney transplant

Method of measurement
Medical records review

2

Description
Serum creatinine

Timepoint
Daily in the first week after kidney transplant then monthly until three months

Method of measurement
Jaffe's reaction

3

Description
Urine volume in the first six hours after transplantation

Timepoint
The first six hours after transplantation

Method of measurement

Urine volume

Secondary outcomes

1

Description
Acute rejection episode in the first three months after transplantation
Timepoint
the first three months after transplantation
Method of measurement
Medical records review

Intervention groups

1

Description
Intervention group: Patients in the treatment arm receive 70 mg/kg vitamin C (at least 3 grams) at last hour before transplant surgery. The calculated dose is diluted in 250 ml of sodium chloride solution (0.45%) and infused over an hour before the transplant
Category
Prevention

2

Description
Control group: Patients in the placebo group, placebo (a saline solution of similar volume) is prescribed at that time.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Transplantation ward, Imam Khomeini Hospital Complex
Full name of responsible person
Simin Dashti-Khavidaki
Street address
Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Simin Dashti-Khavidaki
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Qods ave., Tehran
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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
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mina Borran
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data related to main outcomes of the study will be shared of deidentified IPD as SPSS file.

When the data will become available and for how long

Data will become available three months after publishing the related article. Data will be available for one year.

To whom data/document is available

Data will be available for people working in academic institution.

Under which criteria data/document could be used

An agreement deal between Liver Transplantation research Center of Tehran University of Medical Sciences and people/institution who want to have access to data is needed.

From where data/document is obtainable

The applicant should contact with Professor Simin Dashti-Khavidaki to get these documents or data files. The contact details of Simin Dashti-Khavidaki is: E-mail: dashtis@sina.tums.ac.ir Tel/FAx: 0098 21 66954709

What processes are involved for a request to access data/document

Applicant request will be assessed in the meeting of Liver Transplantation Research Center of Tehran University of Medical Sciences and data will be provided for him/her within 2 months after application acceptance and agreement deal signing.

Comments