Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of protective effects of L-carnitine on the delayed graft function(DGF) in kidney transplant recipients

Protocol summary

Summary

L-carnitine group, aside with the placebo group, after sign of consent form will be included in this study. Patients will be given oral L-carnitine or placebo at a dose of 3000mg within 8-12 hours before kidney transplantation and 3000 mg daily for 3 days after transplantation. Plasma concentration of NGAL will be assessed at baseline and 2,6,12, 24 and 96 hours after transplantation. Plasma concentrations of total L-carnitine will be evaluated at baseline and 96 hours after kidney transplantation. Major parameters related to kidney function including daily levels of BUN, Serum Cr, urine output, serum electrolytes and demographic information of donor and recipient (eg. Age, sex, weight, BMI, PRA, donor SrCr) will be documented. All patients will be followed for need to dialysis during the first week after transplantation, incidence of acute rejection and transplantation complications in first 2 months after transplantation. Comparison of all mentioned measures between intervention group and placebo group at the end of study will show whether L-carnitine improve graft function or not.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312233043N9**
Registration date: **2014-02-10, 1392/11/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-10, 1392/11/21

Registrant information

Name

Simin Dashti-Khavidaki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

dashtis@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of protective effects of L-carnitine on the delayed graft function(DGF) in kidney transplant recipients

Public title

effects of L-carnitine on kidneyl graft function

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: 1. Subjects who are planned to recieve kidney transplantation 2. Subjects of 14-70 years old Exclusion Criteria: 1. Intercurrent acute and severe infections eg: septic shock, myocarditis, acute pancreatitis 2. History of allergy to carnitine or its analogues 3. History of seizure or at high risk for seizure

4. Intercurrent cardiac/hepatic/pulmonary instability during few days after transplantation

Age
From **14 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences

City
Tehran

Postal code

Approval date
2013-11-23, 1392/09/02

Ethics committee reference number
92-03-33-24308

Health conditions studied

1

Description of health condition studied
kidney transplantation

ICD-10 code
T86.1

ICD-10 code description
Kidney transplant failure and rejection

Primary outcomes

1

Description
plasma NGAL level

Timepoint
baseline and 2,6,12, 24 and 96 hours after transplantation

Method of measurement
ELISA

2

Description
plasma carnitine level

Timepoint
baseline and 96 hours after transplantation

Method of measurement
ELISA

3

Description
delayed graft function

Timepoint
during first week after transplantation

Method of measurement
Scr, urine output, need for dialysis

Secondary outcomes

1

Description
Serum sodium concentration

Timepoint
at baseline and daily up to day 7 after transplantation

Method of measurement
ISE

2

Description
serum creatinine concentration

Timepoint
at baseline and daily up to day 7 after transplantation

Method of measurement
Jaffe method

3

Description
acute rejection during 2 months after transplantation

Timepoint
during first and second month

Method of measurement
serum creatinine

4

Description
serum potassium concentration

Timepoint
at baseline and daily up to day 7 after transplantation

Method of measurement
ISE

Intervention groups

1

Description
L-carnitine syrup(500mg/5ml), 3000mg (30ml) day before transplantation and 3000 mg(30ml)(divided in 3 doses) daily for 3 day after transplantation
Category
Treatment - Drugs

2

Description
placebo syrup 30ml,day before transplantation and 30 ml (in three divided doses) daily for 3 days after transplantation
Category
Treatment - Drugs

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
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Younesian
Street address
Tehran University of Medical Sciences
City
Tehran
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
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Mohammad-Reza Khatami
Position
Associeted Professor of nephrology
Other areas of specialty/work
Street address
Nephrology Research Center
City
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Postal code
Phone
+216 6581568
Fax
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Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Atefeh Jafari
Position
Student of Clinical Pharmacy
Other areas of specialty/work
Street address
City
Postal code
Phone
00
Fax
Email
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