

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Aug 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

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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

Associated Professor of nephrology

Other areas of specialty/work

Street address

Nephrology Research Center

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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