

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Evaluation of the effects of L-carnitine on liver function after liver transplantation

#### Protocol summary

##### Study aim

Comparing the incidences of primary graft non-function (PNF), impaired graft function (IPF), acute kidney injury and the length of ICU and hospital stay after liver transplantation between L-Carnitine and placebo groups.

##### Design

Single blind, randomized, placebo-controlled, clinical trial with parallel group design

##### Settings and conduct

Patients on liver transplant waiting list in Imam Khomeini Hospital Complex, are randomly assigned to L-Carnitine or placebo groups. Patients are blinded to allocated group. Demographic, clinical, laboratory liver and kidney function tests and cause of liver failure are gathered from patients' medical record. After transplantation daily liver and kidney function tests are collected from medical record. The number of ICU and hospital stay days will be recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include patients over 14 years with liver cirrhosis who are candidate for the first liver transplantation in Imam Khomeini Hospital Complex and signed informed consent form. Exclusion criteria include children under 14, patients candidate for liver re-transplantation, liver transplant due to acute liver failure, simultaneous multiple organ transplantation, split liver transplantation from living donors or deceased donors, pregnant or lactating women, history of allergy to L-Carnitine and seizure, patients with postoperative unstable conditions such as fever, sepsis, and shock, cardiac instability (ACS / MI), gastrointestinal bleeding, long term need for vasopressor (norepinephrine at doses greater than 0.5 µg /kg/min).

##### Intervention groups

Eligible patients will receive 5mL L-carnitine or placebo syrup twice daily from the time of entry to liver transplant list up to the day of transplantation.

##### Main outcome variables

Patients who have been studied will be assessed for the

incidence of PNF and IPF after liver transplantation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100111003043N12**

Registration date: **2018-07-16, 1397/04/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-16, 1397/04/25**

Update count: **0**

##### Registration date

2018-07-16, 1397/04/25

##### 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

##### Expected recruitment start date

2018-06-28, 1397/04/07

##### Expected recruitment end date

2020-06-27, 1399/04/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effects of L-carnitine on liver function after liver transplantation

**Public title**

"Effect of L-Carnitine on transplanted liver function"

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients over 14 years old with liver cirrhosis who are candidate for the first liver transplantation on the liver transplant list of Imam Khomeini Hospital Complex  
Patient's consent to enter the study

**Exclusion criteria:**

Children under the age of 14 years who are candidate for liver transplantation  
Patients candidate for liver re-transplantation  
Patients who are candidate for liver transplant due to acute liver failure  
Patients undergoing simultaneous multiple organ transplantations (simultaneous liver-kidney transplantation, simultaneous liver-pancreas-kidney transplantation)  
Patients undergoing split liver transplantation from living donors or deceased donors  
Pregnant or lactating women  
History of allergy to L-Carnitine  
Patients with a history of seizure  
Patients with postoperative unstable conditions such as fever, sepsis, and shock, Cardiac instability (ACS/MI), gastrointestinal bleeding, long-term need for vasopressor (norepinephrine at doses greater than 0.5 µg/kg/min)

**Age**

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

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are randomized to L-Carnitine or placebo group by block randomization in sealed envelopes. Allocation will be concealed up to the end of data analysis.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

L-Carnitine and placebo will be provided the same in shape and package. Patients, their physicians and nurses and statistician are blinded to the patients group; however, main investigator who assess the trial's outcome is not blinded.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

**Street address**

Tehran University of Medical Sciences, 16 Azar st, Enghelab st, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

14155-6451

**Approval date**

2018-06-10, 1397/03/20

**Ethics committee reference number**

IR.TUMS.TIPS.REC.1397.008

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

Liver transplantation

**ICD-10 code**

T86

**ICD-10 code description**

Complications of transplanted organs and tissue

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

Evaluation of the occurrence of primary graft non-function after liver transplantation

**Timepoint**

Daily within first week after liver transplantation

**Method of measurement**

Laboratory evaluation of liver function tests including international normalized ratio, serum aminotransferases, serum bilirubin, lactate concentration, blood glucose, venous or arterial blood pH

**2****Description**

Evaluation of the occurrence of initial graft poor function after liver transplantation

**Timepoint**

Daily within first week after liver transplantation

### Method of measurement

Laboratory evaluation of liver function tests including international normalized ratio, serum aminotransferases, serum bilirubin, lactate concentration, blood glucose, venous or arterial blood pH

## Secondary outcomes

### 1

#### Description

Evaluation of occurrence of kidney function after liver transplantation

#### Timepoint

Daily within first week after liver transplantation

#### Method of measurement

Urinary output measurement and laboratory assessment of serum creatinine concentration

### 2

#### Description

Evaluating length of ICU stay

#### Timepoint

Daily from ICU admission to ICU discharge

#### Method of measurement

Counting the days of ICU stay

### 3

#### Description

Evaluating length of hospital stay

#### Timepoint

Daily from transplant surgery to hospital discharge

#### Method of measurement

Counting the days of hospital stay

## Intervention groups

### 1

#### Description

L-Carnitine syrup 500 mg per 5 cc, 500 mg twice a day from the time of entry to the transplant waiting list up to the day of liver transplantation will be used.

#### Category

Treatment - Drugs

### 2

#### Description

Placebo syrup, 5 cc twice a day from the time of entry to the transplant waiting list up to the day of liver transplantation will be used.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

### Name of recruitment center

Liver Transplant Center, Imam-Khomeini Hospital Complex,

### Full name of responsible person

Simin Dashti-Khavidaki

### Street address

Imam-Khomeinin Hospital Complex, Gharib St., Keshavarz Boulevard

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Tehran

### Province

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dashtis@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Sahraian

##### Street address

Deputy of Research, Central organisation of Tehran University of Medical Sciences, Ghods Corner, Keshavarz Boulevard

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+98 21 8163 3686

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msahrai@sina.tums.ac.ir

#### 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**

Behrooz Khajeh

**Position**

Resident of Clinical Pharmacy

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

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Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar St., Enqelab Sq.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Professor

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## Person responsible for updating data

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**Full name of responsible person**

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**Latest degree**

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**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](mailto: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**