

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.

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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

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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

Behrooz Khajeh

Position

Resident of Clinical Pharmacy

Latest degree

Specialist

Other areas of specialty/work

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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