Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 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

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Iran (Islamic Republic of)

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+98 21 6695 4709

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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 envelops. 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
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Imam-Khomeinin 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
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Person responsible for updating data

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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