# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Evaluation of the effectiveness of oral L-carnitine on liver function in children undergoing congenital heart defect repair surgery

## Protocol summary

**Study aim**

Evaluation of serum levels of liver enzymes, bilirubin and albumin and coagulation tests following L-carnitine or placebo use in children undergoing repair surgery for congenital heart defects

**Design**

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. Random number table was used for randomization

**Settings and conduct**

Children who are scheduled for repair of congenital heart defects, both cyanotic and non-cyanotic, in the heart surgery room of Modares Hospital will be included in the study if they meet the inclusion criteria. Clinical evaluation includes alertness as well as the possible presence of ascites at the pre-visit, as well as liver enzyme and bilirubin and albumin tests and coagulation tests. On the first and seventh day of post operative hospitalization in the ICU, the clinical evaluation and the aforementioned tests are performed again. In addition, demographic data as well as operating room period characteristics such as pump and clamp duration as well as ICU data such as intubation period and hospitalization period are recorded.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: 1- Age 6 to 60 months 2- Heart repair surgery under the pump 3- Conscious consent of parents Exclusion criteria: 1- Off-pump operation 2- Known allergy to L-carnitine 3- Severe liver failure (liver enzymes more than twice normal) 4- Emergency operation

**Intervention groups**

The intervention group (L) is given 100 mg per kg of oral L-carnitine the night before surgery. Control group (P) is given normal saline as a placebo.

**Main outcome variables**

Tests for liver enzymes, bilirubin and albumin, and coagulation tests

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180724040575N2**
Registration date: **2020-09-28, 1399/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-28, 1399/07/07**
Update count: **0**

**Registration date**

2020-09-28, 1399/07/07

**Registrant information**

**Name**

kamal fani

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 2207 4095

**Email address**

kamalfani@sbmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-10-23, 1398/08/01

**Expected recruitment end date**

2020-10-22, 1399/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effectiveness of oral L-carnitine on liver function in children undergoing congenital heart defect repair surgery

**Public title**
The effect of carnitine on liver function
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age 6 to 60 months Cardiac repair surgery under the pump Conscious consent of parents
**Exclusion criteria:**
Off pump operation Known allergy to L-carnitine Severe liver failure (liver enzymes more than twice normal) Emergency operation
**Age**
From **6 months** old to **60 months** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **3**
Liver enzymes, coagulation tests, bilirubin and albumin
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The study was designed as a randomized clinical trial using a random number table
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Patients, parents, and those involved in surgery and subsequent care and data recorders are blind to the study groups.The parents confirm the consent but are not aware of being in which group. Based on randomization, the drug or placebo is given to the patient the night before the operation. Members of the intraoperative and postoperative care team as well as data recorders are not aware of the study group.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of shahid beheshti University of Medical Sciences
**Street address**
Taleghani Hospital, velenjak, Tehran. Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
19969111151
**Approval date**
2019-11-24, 1398/09/03
**Ethics committee reference number**
IR.SBMU.RETECH.REC.1398.418

## Health conditions studied

**1**

**Description of health condition studied**
Surgery for repair of congenital heart lesions
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Alanine aminotransferase
**Timepoint**
Before, the first and seventh day after surgery
**Method of measurement**
Measuring the amount in the blood sample

**2**

**Description**
aspartate aminotransferase
**Timepoint**
Before, the first and seventh day after surgery
**Method of measurement**
Measuring the amount in the blood sample

**3**

**Description**
alkaline phosphatase
**Timepoint**
Before, the first and seventh day after surgery
**Method of measurement**
Measuring the amount in the blood sample

**4**

**Description**
lactate dehydrogenase
**Timepoint**
Before, the first and seventh day after surgery

**Method of measurement**
Measuring the amount in the blood sample

**5**

**Description**
Bilirubin
**Timepoint**
Before, the first and seventh day after surgery
**Method of measurement**
Measuring the amount in the blood sample

**6**

**Description**
Albumin
**Timepoint**
Before, the first and seventh day after surgery
**Method of measurement**
Measuring the amount in the blood sample

**7**

**Description**
Prothrombin time
**Timepoint**
Before, the first and seventh day after surgery
**Method of measurement**
Measuring the amount in the blood sample

**8**

**Description**
partial thromboplastin time
**Timepoint**
Before, the first and seventh day after surgery
**Method of measurement**
Measuring the amount in the blood sample

**9**

**Description**
international normalization ratio
**Timepoint**
Before, the first and seventh day after surgery
**Method of measurement**
Measuring the amount in the blood sample

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Administration of 100 mg / kg oral L-carnitine, the night before surgery
**Category**
Prevention

**2**

**Description**
Control group: Administration of 1 ml per kg oral serum of normal saline, the night before surgery
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Modarres Hospital
**Full name of responsible person**
Kamal Fani
**Street address**
Modarres Hospital, Saadat abad Ave., Tehran, Iran
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Dr. Afshin Zarghi
**Street address**
Taleghani Hospital,Velenjak Ave.,Tehran, Iran
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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**
Shahid Beheshti 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**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Kamal Fani
**Position**
Assistant professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be 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