Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

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+98 21 2207 4095

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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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1996911151
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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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Modarres hosp., Saadat abad Ave.,Tehran, Iran
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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