Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Effect of l-carnitine supplementation on inflammatory markers, serum glucose and lipids in hemodialysis children

Protocol summary

Study aim
In this study hemodialysis children will be assessed in order to determine the effects of l-carnitine supplementation on serum concentrations of inflammatory factors,lipid profile and serum glucose.

Design
This study will be conducted as a randomized controlled trial. Subjects were randomly divided into two groups including 15 subjects (receiving l-carnitine supplement) and control (placebo). stratified blocked randomization method will be used to randomly assign patients to the two groups.

Settings and conduct
Subjects were randomly divided into two groups including 15 subjects intervention and control group.For each patient anthropometric measurements and general characteristics will be assessed at the baseline and end of the study will be filled. 24-h food record questionnaire in order to assess of food intake and pediatrics quality of life will be complete at the beginning and end of trial. 7 cc fasting blood samples from each patient will be taken at the beginning and end of the intervention. researcher and patient will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 6 -18 years old; at least 2 times a week dialysis; three months pass after dialysis at least; deficiency of carnitine; Exclusion criteria: pregnancy; use of lipid lowering and ...drugs; autoimmune, infectious...disease and disorders;nutritional support;use of l-carnitine in past 3 month

Intervention groups
Intervention group will receive daily 50 mg per kg/bw l-carnitine supplement from Alborz daru company for 8 weeks.All the patients will be monitored for consumption of syrup. The control group will receive daily 50 mg per kg/bw of placebo from The Institute of Pharmaceutical Sciences of Tehran university of medical science for 8 weeks.All the patients will be monitored for consumption of syrup.

Main outcome variables
inflammatory markers;serum glucose;lipid profile;apo A

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170202032367N2**
Registration date: **2019-08-11, 1398/05/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-11, 1398/05/20**
Update count: **0**

Registration date
2019-08-11, 1398/05/20

Registrant information

Name
Hossien Imani

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 8895 5975

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h-imani@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-11, 1398/04/20

Expected recruitment end date
2019-10-22, 1398/07/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of l-carnitine supplementation on inflammatory markers, serum glucose and lipids in hemodialysis children

Public title

Effect of l-carnitine supplementation on inflammation, blood glucose and lipids in hemodialysis children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

at least 2 times a week dialysis three months pass after dialysis at least plasma carnitine to carnitine free ratio greater than 0.4 (indicating a lack of carnitine) desiring to participate in this study

Exclusion criteria:

pregnanacy use of non-steroidal and steroidal anti-inflammatory, lipid lowering and beta-blocker medications autoimmune diseases, infectious, inflammatory disease, cardiovascular disease, thyroid disorders, thrombocytopenia nutritional support (enteral and parenteral nutrition)

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized into two groups: the l-carnitine supplementation group and the placebo group. stratified blocked randomization method will be used to randomly assign patients to the two groups

Blinding (investigator's opinion)

Double blinded

Blinding description

participants, researcher and outcome assessor will be kept blind in this study

Placebo

Used

Assignment

Parallel

Other design features

The assessment of improvement in physical health, mental health, performance and quality of life, and reduction of complications are also among the goals.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Tehran university of medical science

Street address

Keshavarz Beulvard, Naderi St, Hojjatdoust alley, No 44 , schools of nutritional sciences and dietetics

City

Tehran

Province

Tehran

Postal code

1416643931

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.TUMS.VCR.REC.1398.102

Health conditions studied

1

Description of health condition studied

Chronic kidney disease, stage 5

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

2

Description of health condition studied

dialysis complications

ICD-10 code

Y84.1

ICD-10 code description

Kidney dialysis as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

3

Description of health condition studied

Dialysis-induced inflammation

ICD-10 code

T85.7

ICD-10 code description

Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts

4

Description of health condition studied

Hyperlipidemia

ICD-10 code

E78.5
ICD-10 code description
Hyperlipidemia, unspecified

5

Description of health condition studied
hyperglycemia
ICD-10 code
R73.9
ICD-10 code description
Hyperglycemia, unspecified

6

Description of health condition studied
carnitine deficiency
ICD-10 code
E71.448
ICD-10 code description
Other secondary carnitine deficiency

7

Description of health condition studied
Disorder of fatty-acid metabolism
ICD-10 code
E71.30
ICD-10 code description
Disorder of fatty-acid metabolism, unspecified

Primary outcomes

1

Description
interleukin-6
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA assay

2

Description
high sensitivity c-reactive protein
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Immunoturbidimetry

3

Description
total cholesterol
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
enzymatic

4

Description
serum tryglycerides
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
enzymatic

5

Description
low density lipoprotein cholesterol
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
enzymatic

6

Description
high density lipoprotein cholesterol
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
enzymatic

7

Description
serum glucose
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
enzymatic

8

Description
apolipoprotein A
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
enzymatic

9

Description
serum carnitine
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
ELISA assy

10

Description
Serum albumin
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic

Secondary outcomes

1

Description
quality of life
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
questionnare (PedsQL)

2

Description
nutritional status (calorie and nutrients intake)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Food record questionnaire

3

Description
Anthropometric index(weight, height,WHR and Body Mass Index)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Analogue scale for weight, height, WHR and CDC chart

4

Description
acyl carnitine
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
spectrometry

Intervention groups

1

Description
Intervention group: Intervention group will receive daily 50 mg per kg of body weight l-carnitine supplement for 8 weeks. L-carnitine syrups will be purchased from the Alborz daru Company. All the patients will be monitored for consumption of syrup by weekly checklists and recall messages
Category
Treatment - Drugs

2

Description
ControThe control group will receive daily 50 mg per kg of body weight of placebo for 8 weeks. placebo syrups will be purchased from the The Institute of Pharmaceutical Sciences of Tehran university of medical scienced . All the patients will be monitored for consumption of syrup by weekly checklists and recall messages.l group:
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahrami Children Hospital
Full name of responsible person
Seyyed Yusef Mojtahedi
Street address
Bahrami hospital, Ansar alHosein st, kianee ave, Damavand st, Tehran, IRAN
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Province
Tehran
Postal code
1641744991
Phone
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Fax
Email
hosp_bahrami@tums.ac.ir
Web page address

2

Recruitment center
Name of recruitment center
children's medical center
Full name of responsible person
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Children’s Medical Center, No 63, Gharib Ave, Keshavarz Blv
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Province
Tehran
Postal code
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Phone
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Fax
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Email
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3

Recruitment center
Name of recruitment center
Mofid children's hospital
Full name of responsible person
Beheshte olang
Street address
District 3, Shariati St
City
Tehran
Province
Tehran
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15514- 15468

Phone
+98 21 2222 7021
Fax
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Street address
sixth floor, central organization of Tehran university of medical sciences, ghods st, keshavarz blvd, Tehran
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Postal code
1417653761
Phone
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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
Dr Hossein Imani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Keshavarz Beulvard, Naderi St, Hojjatdoust alley, No 44 , schools of nutritional sciences and dietetics
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Phone
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Assistant Professor
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Other areas of specialty/work
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Street address
Keshavarz Beulvard, Naderi St, Hojjatdoust alley, No 44 , schools of nutritional sciences and dietetics
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Tehran
Postal code
1416643931
Phone
+98 21889900285
Email
h-imani@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Hamedi
Position
student
Latest degree
Master
Other areas of specialty/work
Nutrition
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Keshavarz Beulvard, Naderi St, Hojjatdoust alley, No 44 , schools of nutritional sciences and dietetics
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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