Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

The Effects of Coenzyme Q10 Supplementation in Pediatrics with Chronic Kideny Disease stage 2 - 4 : A Randomized, Paralleled, Double blind, Controlled clinical trial

Protocol summary

Study aim
Proposing a new drug intervention to improve renal function.

Design
Randomized, paralleled, Double blind, controlled clinical trial with sample size of 60 patients

Settings and conduct
After entering the trial, patient will be randomly allocated to intervention and control groups by block randomization process. Physician and patients will be blind in this trial. Blood and urine samples will be taken at time 0 and three months after intervention and results are compared before and after the study and between both groups. This study will be conducted locally in Ali Asghar Children's Hospital.

Participants/Inclusion and exclusion criteria
Children diagnosed with Chronic Kidney Disease (CKD) stages 2 to 4 Entering criteria: 1.Age between 2 to 18 years old 2.Children diagnosed with CKD stages 2 to 4 based on estimated Glomerular Filtration Rate (eGFR) Criteria for exclusion: 1.Liver disease 2.Autoimmune diseases 3.Kidney transplantation in last 6 months 4.Taking Corticosteroids and immunosuppressive medication

Intervention groups
After entering the trial, patient will be randomly allocated to intervention and control groups. Patients in the intervention group will take Q10, 3 mg per kg up to 100 mg daily adjuvant to their routine medication. Patients in control group will only receive their routine medication.

Main outcome variables
Blood Urea Nitrogen (BUN) level serum Creatinine level estimated Glomerular Filtration Rate (eGFR) Urine Protein level

General information

Reason for update

Acronym
co Q10

IRCT registration information
IRCT registration number: **IRCT20190722044303N1**
Registration date: **2019-12-25, 1398/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-25, 1398/10/04**
Update count: **0**

Registration date
2019-12-25, 1398/10/04

Registrant information

Name
Pedram Shayesteh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2214 0806

Email address
peddy.sh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-22, 1398/05/31

Expected recruitment end date
2020-02-19, 1398/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Effects of Coenzyme Q10 Supplementation in Pediatrics with Chronic Kideny Disease stage 2 - 4 : A Randomized, Paralleled, Double blind, Controlled clinical trial

Public title
The Effects of Coenzyme Q10 Supplementation in Pediatrics with Chronic Kideny Disease : A Randomized, Paralleled, Double blind, Controlled clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 2 to 18 years old Diagnosed with Chronic Kidney Disease stage 2 - 4 according to estimated Glomerular Filtration Rate (eGFR) findings

Exclusion criteria:
Liver disease Chronic pulmonary disease Autoimmune disease Gastrointestinal dysfunction with the need for Parenteral nutrition Kidney transplantation in last 6 months Taking Antioxidants such as Vit E , L-Carnitine, or Omega 3 supplements in past 3 months Taking corticosteroids and/or immunosuppressive medication

Age
From **2 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into control and intervention groups using Blocked Randomization method. In this method, computer generated block sizes of 4 with equal probability will be used to enter eligible patients into one of the groups, intervention (Group B) and control (Group A). Initially one of the blocks will be randomly selected and the blocks will be repeatedly used to enter all eligible patients into one of the two groups. Patients in the intervention group (Group B) will be treated with the usual treatment regimen, plus Co Q10, 3 mg / kg and up to 100 mg daily for 3 months. In the control group, patients will receive only the usual treatment regimen.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the physician and participants are blind. After the diagnosis of the disease, the physician will give the patients the envelopes on which A or B are written. The patient will deliver the envelope to the investigator, and after checking the inclusion and exclusion criteria of the study, the patient will be assigned to either the control (A) or intervention (B) groups based on the envelopes. Only the investigator knows which group is intervention and which group is control.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran university of medical sciences

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2019-07-16, 1398/04/25

Ethics committee reference number
IR.IUMS.REC.1398.407

Health conditions studied

1

Description of health condition studied
Chronic Kidney Disease

ICD-10 code
N18

ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Blood Urea Nitrogen level

Timepoint
Before starting an intervention and three months after taking co enzyme Q10 supplement

Method of measurement
Blood test, Photometric kit

2

Description

Creatinine level

Timepoint

Before starting an intervention and three months after taking co enzyme Q10 supplement

Method of measurement

Blood test, photometric kit

3

Description

eGFR

Timepoint

Before starting an intervention and three months after taking co enzyme Q10 supplement

Method of measurement

Calculation based on blood Creatinine and patient's height

4

Description

Proteinuria

Timepoint

Before starting an intervention and three months after taking co enzyme Q10 supplement

Method of measurement

Urine test, Dipstick

Secondary outcomes

1

Description

C-Reactive Protein (CRP) level

Timepoint

Before starting the intervention and 3 months after taking co enzyme Q10 supplement

Method of measurement

Blood test, Agglutination method

2

Description

Erythrocyte Sedimentation Rate (ESR) level

Timepoint

Before starting the intervention and 3 months after taking co enzyme Q10 supplement

Method of measurement

Blood test, Photometric kit

3

Description

Fasting blood Glucose level

Timepoint

Before starting the intervention and 3 months after taking co enzyme Q10 supplement

Method of measurement

Blood test, Photometric test

4

Description

Alanine Aminotransferase (ALT) level

Timepoint

Before starting the intervention and 3 months after taking co enzyme Q10 supplement

Method of measurement

Blood test, photometric kit

5

Description

Aspartate Aminotransferase (AST) level

Timepoint

Before starting the intervention and 3 months after taking co enzyme Q10 supplement

Method of measurement

Blood test, photometric kit

6

Description

Blood Triglyceride level

Timepoint

Before starting the intervention and 3 months after taking co enzyme Q10 supplement

Method of measurement

Blood test, photometric kit

7

Description

Low Density Lipoprotein (LDL) level

Timepoint

Before starting the intervention and 3 months after taking co enzyme Q10 supplement

Method of measurement

Blood test, photometric kit

8

Description

High Density Lipoprotein (HDL) level

Timepoint

Before starting the intervention and 3 months after taking co enzyme Q10 supplement

Method of measurement

Blood test, photometric kit

9

Description

Total Cholesterol level

Timepoint

Before starting the intervention and 3 months after taking co enzyme Q10 supplement

Method of measurement

Blood test, photometric kit

10

Description

Urine protein level

Timepoint

Before starting the intervention and 3 months after

taking co enzyme Q10 supplement

Method of measurement

Urine test, Dipstick method

Intervention groups

1

Description

Intervention group: After entering the trial, patients will be prescribed to take co enzyme Q10 supplement from Nutri Century Corporation 3 mg per kg up to 100 mg daily adjuvant to their routine medication.

Category

Treatment - Drugs

2

Description

Control group: After entering the trial, patients will only receive their routine medications without Q10. Blood and urine tests will be taken at time 0 and three months after taking Q10.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali asghar children's hospital

Full name of responsible person
Pedram Shayesteh

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Zafar street , Modarres Highway

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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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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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
Iran University of Medical Sciences

Full name of responsible person
Pedram Shayesteh

Position
Student

Latest degree
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Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available