Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effects of Coenzyme Q10 on the serum concentration of interleukin 6 and interleukin 33 in hemodialysis patients

Protocol summary

Summary

Objectives: The main goal of this study is evaluation of anti-inflammatory effects of coenzyme Q10 (CoQ10) in hemodialysis patients. Design: This study is a randomized single blind (the researchers who measure the serum concentration of interleukins and analyze results have no information about the group assignment of the patients) clinical trial. One hundred thirty hemodialysis patients will be recruited from 2 dialysis centers. Setting and conduct: Patients will be assigned to the intervention or control group using the simple blocked randomization. Duration of the study is 3 months. Participants: Patients undergoing regular hemodialysis for at least 3 months will be entered to the study. Patients with active infection and who are consuming anti-inflammatory drugs or warfarin will be excluded. Intervention: Patients will receive CoQ10 capsules at dose of 100 mg daily in the intervention group. In the control group patients will only receive their routine drugs. Main outcome measures: Primary outcome variables: Serum concentration of interleukin 6 and interleukin 33 Secondary outcome variable: Adverse effects

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061722637N2**
Registration date: **2017-05-21, 1396/02/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-21, 1396/02/31

Registrant information

Name
Naemeh Nikvarz
Name of organization / entity
Kerman University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 34 3132 5017
Email address
nnikvarz@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source
Vice Chancellor for Research of Kerman University of Medical Sciences

Expected recruitment start date

2017-02-25, 1395/12/07

Expected recruitment end date

2017-08-25, 1396/06/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Coenzyme Q10 on the serum concentration of interleukin 6 and interleukin 33 in hemodialysis patients

Public title

Evaluation of the effects of Coenzyme Q10 on the serum concentration of interleukin 6 and interleukin 33 in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who are undergoing regular hemodialysis for at least 3 months will be entered.

Exclusion criteria: Being in active infection phase, having autoimmune diseases, consuming immunosuppressive medications or warfarin, pregnancy, breast feeding

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Office of Vice chancellor for research, Ebn-e-sina Street

City
Kerman

Postal code

Approval date
2017-02-18, 1395/11/30

Ethics committee reference number
IR.KMU.REC.1395.862

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease (Hemodialysis)

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5 Chronic uraemia End stage kidney disease: in allograft failure NOS on dialysis without dialysis or transplant

Primary outcomes

1

Description
Serum concentration of interleukin 6

Timepoint
At baseline and at the end of the study

Method of measurement
ELISA kit

2

Description
Serum concentration of interleukin 33

Timepoint
At baseline and at the end of the study

Method of measurement
ELISA kit

Secondary outcomes

1

Description
Adverse effects

Timepoint
During the study

Method of measurement
Patients' report

Intervention groups

1

Description
Intervention 1: CoQ10 100 mg oral capsules, Dosage: 100 mg once daily, Duration: Three months

Category
Treatment - Drugs

2

Description
Intervention 2 (control group): No treatment, Duration: Three months

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shafa Hospital

Full name of responsible person
Naemeh Nikvarz

Street address
Shafa Hospital, Kowsar Boulevard

City
Kerman

2

Recruitment center
Name of recruitment center
Javad-ol Aemeh Dialysis Center
Full name of responsible person
Naemeh Nikvarz
Street address
25th Alley, North Aboozar Street
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
Street address
Office of Vice chancellor for research, Ebn-e-sina Street
City
Kerman
Grant name
Grant code / Reference number
95000191
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Zahra Sharifi Negad
Position
Pharmacy student
Other areas of specialty/work
Street address
Faculty of pharmacy, Haft-Bagh Road
City
Kerman
Postal code
7616911319
Phone
+98 34 3132 5000
Fax
+98 34 3132 5003
Email
zahrasharifi12@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Naemeh Nikvarz
Position
Clinical Pharmacy Specialist
Other areas of specialty/work
Street address
Shafa Hospital, Kowsar Boulevard
City
Kerman
Postal code
7618751151
Phone
+98 34 3121 7243
Fax
+98 34 3132 5003
Email
nnikvarz@kmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Naemeh Nikvarz
Position
Clinical Pharmacy Specialist
Other areas of specialty/work
Street address
Shafa Hospital, Kowsar Boulevard
City
Kerman
Postal code
7618751151
Phone
+98 34 3121 7243
Fax
+98 34 3132 5003
Email
nnikvarz@kmu.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty