Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of Coenzyme Q10 effects on cognitive level of hemodialysis patients in Kowsar hospital, Semnan, 2015

Protocol summary

Summary

Objective Cognitive impairment is a common complication in patients undergoing chronic hemodialysis. The aim of this study is to investigate the effect of CO Q 10 on cognitive impairment in these patients. Study design: This study designed as a Randomized Double Blind Placebo – Controlled clinical trial in phase 2-3. Study population and sample size: Eighty patients who undergoing chronic hemodialysis in Semnan Kowsar Hospital are enrolled in study. The main inclusion and exclusion criteria: Inclusion criteria: Chronic renal disease which need to hemodialysis. Exclusion criteria: Have not any exclusion criteria. Interventions Patients who fulfilled inclusion criteria will undergo the Mini Mental State Examination (MMSE), then randomly divided into two groups, the intervention group will receive CO Q10, 100 mg daily and control group placebo. Patients in both groups after the 90 days again undergo the Mini Mental State Examination and results of before and after the intervention will be analyzed. The intervention time At the beginning of the study and 90 days after administrating of drug or placebo Outcome of study Alteration in cognitive status according to the test result.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014103019758N1**
Registration date: **2014-12-25, 1393/10/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-25, 1393/10/04

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research and Technology, Semnan University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-07-21, 1394/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Coenzyme Q10 effects on cognitive level of hemodialysis patients in Kowsar hospital, Semnan, 2015

Public title

Effects of Coenzyme Q10 on cognitive level of hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who undergoing hemodialysis.
Exclusion criteria: None

Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee, Semnan University of Medical Sciences
Street address
Basidj Boulevard
City
Semnan
Postal code
Approval date
2014-12-07, 1393/09/16
Ethics committee reference number
93/534890

Health conditions studied

1

Description of health condition studied
Cognitive state
ICD-10 code
F06.7
ICD-10 code description
Mild cognitive disorder

Primary outcomes

1

Description
Cognitive state
Timepoint
90 Days after intervention
Method of measurement
Interview and standars questionnaire Mini-mental state examination

Secondary outcomes

empty

Intervention groups

1

Description
Patients in case group after mini-mental state examination will receive Coenzym Q10 daily 100 mg, after that mini-mental state examination will be carried out again.
Category
Treatment - Drugs

2

Description
Patients in control group after mini-mental state examination will receive placebo for 90 days and after that mini-mental state examination will be carried out again.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital, Dialysis center
Full name of responsible person
Dr. Shahb Rafati
Street address
Amin Ave., Basidj Boulevard
City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
emnan University of Medical Sciences, Vice Chancellor of Research and Technology
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Dr. Mohamad Reza Asgari
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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
emnan University of Medical Sciences, Vice Chancellor of Research and Technology
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

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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