

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Mohamad Reza Tamadon

Name of organization / entity

Semnan University of Medical Sciences

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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

Full name of responsible person

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**Contact****Name of organization / entity**

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Full name of responsible person

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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