Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of coenzyme Q10 and placebo on the severity of depressive symptoms in the treatment of patients with (major) depression

Protocol summary

Study aim

The purpose of this study is evaluation of the effect of co-enzyme Q10 as adjuvant therapy in patients with depression.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 74 patients. Randomization is done by permutation block method. In each block, depending on the sample size, five patients are admitted. Random allocation help software is also used.

Settings and conduct

The study is done at Psychology clinic of Rasoul Akram hospital in Tehran. The study population is patients with depression. The study is done in a double-blind manner. Patients based on permutation block method divided into two groups of intervention and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients between 18-65 years old; patients with diagnosed depression based on Beck score. Non-inclusion criteria: patients with mixed episodes of depression and manic or hypomanic phase; patients with severe disease; patients who administrated antidepressant agents during 1 month ago; patients who administrated any antioxidant agents or supplements during 1 month ago; pregnant patients.

Intervention groups

The intervention group receives 200 mg/day of co-enzyme Q10 for 8 weeks. The control group receive a placebo completely similar to drug in appearance for 8 weeks.

Main outcome variables

Severity of depressive symptoms in patients based on Beck Inventory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161204031229N5**
Registration date: **2021-09-13, 1400/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-13, 1400/06/22**
Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-01, 1400/06/10

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of coenzyme Q10 and placebo on the severity of depressive symptoms in the treatment of patients with (major) depression

Public title

The effect of Coenzyme Q10 in depressed patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 18-65 years old Patients with diagnosed depression

Exclusion criteria:

Patients with mixed episodes of depression and manic or hypomanic phase Patients with severe disease Patients who administrated antidepressant agents during 1 month ago Patients who administrated any antioxidant agents or supplements during 1 month ago Pregnant patients

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the Restricted randomization method of block randomization. All blocks are the same size, and in this two-group experiment we will have blocks of size 6 (including 3 participants in the intervention and 3 participants in the control groups). Random allocation software is also used to randomize random sequence production software (Random allocation software). For concealment, we also use concealment allocation.

Blinding (investigator's opinion)

Triple blinded

Blinding description

All participants in the study, including participants, clinical caregivers, researchers, etc., are kept blind. Of course, before starting the study, informed consent is obtained from the participants. But because drugs and placebo are similar in shape and different in content, practically no one knows their true nature

Placebo

Used

Assignment

Parallel

Other design features

Neither the participants or the experimenters know who is receiving a particular treatment and the patients are randomized into intervention group or placebo group by cards shuffling method.

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, Hemmat Highway, Tehran

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Approval date

2021-04-18, 1400/01/29

Ethics committee reference number

IR.IUMS.REC.1400.077

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.9

ICD-10 code description

Major depressive disorder, single episode, unspecified

Primary outcomes

1

Description

Depression severity

Timepoint

Before the intervention, at the 4th week of intervention, at the 8th week of intervention

Method of measurement

By beck inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 200 mg coenzyme Q10 twice daily plus standard treatment of depression for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Placebo plus standard treatment for depression for 8 weeks
Category
Placebo

Recruitment centers

1

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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

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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