

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Name

Azadeh Eshraghi

Name of organization / entity

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Country

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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

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

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

Recruitment center

Name of recruitment center

Hazrate Rasool Akram Hospital

Full name of responsible person

Azadeh Eshraghi

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Niayesh street, Satarkhan street

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Sponsors / Funding sources

1

Sponsor

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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

Azade Eshraghi

Position

Assistant professor

Latest degree

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Person responsible for updating data

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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