

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effect of coenzyme Q10 on oxidative and nitrosative stress biomarkers in depression phase of bipolar disorder

Protocol summary

Summary

The purpose of this study is evaluation of the effect of co-enzyme Q10 as adjuvant therapy in depression phase of bipolar disorder patients. This study is a double-blinded randomized study that is done on 74 patients with bipolar disorder depression. Patients are randomly divided into two groups of intervention and placebo. The intervention group receive 200 mg/day of co-enzyme Q10 for 8 weeks. The placebo group receive a placebo completely similar to drug in appearance for 8 weeks. Serum level of TNF-a, IL-10, IL-6, total antioxidant capacity, lipid peroxidation and thiol groups are measured in both groups (intervention and placebo) at the start of the study and 8th week of study and the effect of drug and placebo is evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016103022965N5**

Registration date: **2017-06-25, 1396/04/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-25, 1396/04/04

Registrant information

Name

Maryam Mehrpoya

Name of organization / entity

School of Pharmacy, Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of coenzyme Q10 on oxidative and nitrosative stress biomarkers in depression phase of bipolar disorder

Public title

Effect of coenzyme Q10 on oxidative and nitrosative stress

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients between 18-65 years old; patients with diagnosed bipolar depression based on DSM-5 and MADRS score equal to or more than 7
exclusion criteria: patients with anxiety disorder not related to bipolar disorder; 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; patients who did not administrated

drug or placebo regularly at least in 80% of study duration; pregnant patients; nursing patients

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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 simple randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Hamedan University of Medical Sciences

Street address

Hamedan, Pazhoohesh Crossroad, In front of the Luna park, Hamedan University of Medical Sciences

City

Hamedan

Postal code

Approval date

2017-04-22, 1396/02/02

Ethics committee reference number

IR.UMSHA.REC.1396.89

Health conditions studied

1

Description of health condition studied

Depression phase of bipolar disorder

ICD-10 code

F31.3

ICD-10 code description

Bipolar affective disorder, current episode mild or

moderate depression

Primary outcomes

1

Description

TNF-a

Timepoint

before the intervention, at the 8th week of intervention

Method of measurement

serum level

2

Description

interleukin 6

Timepoint

before the intervention, at the 8th week of intervention

Method of measurement

serum level

3

Description

interleukin 10

Timepoint

before the intervention, at the 8th week of intervention

Method of measurement

serum level

4

Description

Total antioxidant capacity

Timepoint

before the intervention, at the 8th week of intervention

Method of measurement

serum level

5

Description

Thiol groups

Timepoint

before the intervention, at the 8th week of intervention

Method of measurement

serum level

6

Description

Lipid peroxidation

Timepoint

before the intervention, at the 8th week of intervention

Method of measurement

serum level

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: 200mg coenzyme Q10 twice daily plus standard treatment of bipolar depression for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo plus standard treatment for bipolar depression for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam's clinic

Full name of responsible person

Leila Jahangard

Street address

Imam's clinic, Mirzade Street, Hamadan

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Hamadan University of Medical Sciences

Full name of responsible person

Alireza Ahmadi

Street address

Hamedan University of Medical Sciences, In front of Luna park, Pazhouhesh Cross , Hamadan

City

Hamedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Hamadan 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

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Mehrpooya

Position

PhD of clinical pharmacy,Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Fateme Yasrebifar

Position

student

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Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

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Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty