Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of coenzyme Q10 in depression phase of bipolar disorder patients as adjuvant therapy

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. The depression symptoms severity of patients is measured by Montgomery Asberg Depression Rating Scale(MADRS) in both groups (intervention and placebo) at the start of the study,4th week and 8th week of study and the effect of drug and placebo is evaluated based on MADRS.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016092622965N4**
Registration date: **2017-03-20, 1395/12/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-20, 1395/12/30

Registrant information

Name

Maryam Mehrpooya

Name of organization / entity

School of Pharmacy,Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3821 8684

Email address

m.mehrpoya@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Hamedan University of Medical Sciences

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2017-10-02, 1396/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of coenzyme Q10 in depression phase of bipolar disorder patients as adjuvant therapy

Public title

The effect of Coenzyme Q10 in bipolar disorder

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 adminsitrated 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
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 cards shuffling 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
2016-09-17, 1395/06/27

Ethics committee reference number
IR.UMSHA.REC.1395.292

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
depression severity

Timepoint
before the intervention, at the 4th week of intervention, at the 8th week of intervention

Method of measurement
MADRS

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

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
Hamedan University of Medical Sciences

Full name of responsible person
Dr Bashirian

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
Hamedan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Maryam Mehrpooya

Position
Assistant Professor/ PhD of clinical pharmacy

Other areas of specialty/work

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

City
Hamedan

Postal code

Phone
+98 81 3838 1590

Fax

Email
m_mehrpooya2003@yahoo.com

Web page address

Person responsible for updating data

Contact

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