

# 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)

###### Phone

+98 81 3821 8684

###### Email address

m.mehrpooya@umsha.ac.ir

###### 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

#### Street address

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

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#### Fax

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m\_mehrpooya2003@yahoo.com

#### Web page address

## Person responsible for scientific 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 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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**City**

Hamedan

**Postal code****Phone**

00

**Fax****Email****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*